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and Patient Behavior**

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Noncompliant?**

**Health Diaries: Strategies for Compliance and Relation to
Other Measures**

Patient Characteristics That Influence Physician Behavior

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Psychosocial Factors Affecting Adherence to Medical Regimens in a Group of Hemodialysis Patients

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The present research was designed to identify psychosocial correlates of adherence among patients receiving hemodialysis at two outpatient clinics. The 116 participants were interviewed concerning their knowledge of treatment, health beliefs, treatment history, social support, personal characteristics, and adherence to the medication, diet and fluid-intake aspects of the regimen. In addition, medical record data were obtained on serum phosphorus and serum potassium levels, and on between-dialysis weight gains. The magnitude of relationships between predictors and adherence measures varied, depending on the method used to measure adherence. For the self-report measures, beliefs concerning the efficacy of the behavior and barriers to the behavior, along with reported family problems, proved to be consistent predictors. Other beliefs and characteristics did not contribute significantly. For the medical chart information, however, the predictive factors were less consistent. In general, situational factors seem to be the major contributors to patient adherence, and adherence itself is seen as a complex and multidimensional phenomenon.

FOR PATIENTS with end-stage renal disease, replacement of aspects of the different functions of the kidney is obtained through hemodialysis, dietary management and medication. Hemodialysis removes toxic fluids and metabolic end products from the blood stream by use of an

artificial kidney machine. Unfortunately, such treatments alone are usually not sufficient to prevent or alleviate the symptoms that result from kidney failure, and most patients are also required to follow a complex and trying diet regimen, which restricts protein, sodium, potassium and fluid intake. The objective of dietary management is to assist hemodialysis treatments by reducing the amounts of urea, creatinine and electrolytes (especially potassium, sodium and phosphate) that must be excreted.^{1,2} Abuse of dietary restrictions can lead to a buildup of toxic fluids and metabolic end products in the blood stream, which may, in turn, result in nausea, weakness, cardiovascular problems and even death. In addition to dietary

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controls, most patients are requested to take phosphate-binding medications, and many patients are also given vitamin supplements, drugs to reduce blood pressure, drugs to prevent blood clotting and other medications as well.² Thus, successful treatment of end-stage renal disease depends to a large degree upon the patient's willingness to cooperate with a therapeutic plan that is often very restrictive and difficult to follow.

However, despite the adverse consequences associated with poor compliance, there is substantial evidence of considerable abuse of dietary and medication regimens by hemodialysis patients.³⁻¹⁶ An averaging of compliance rates from many studies^{10, 12, 13, 15, 16} reveals that about one third of all patients fail to comply with both between-dialysis fluid limitations (measured by between-dialysis weight gains) and diet restrictions (measured by serum potassium levels), and about half do not follow instructions for taking phosphate-binding medication (measured by serum phosphorus levels).

Determinants of Compliance

Relatively few of the studies reported in the literature have attempted to identify factors associated with compliance behaviors among hemodialysis patients. Furthermore, a common aim of many of these studies was to identify variables that could be used as criteria to select patients for a limited number of treatment slots; as a result, much of this research is descriptive, focusing mainly on characteristics of the patient (e.g., age, sex, socioeconomic status, intelligence, psychologic functioning) and upon features of the patient's social situation (e.g., family size, quality of home environment), variables that are relatively enduring and immutable.

A seemingly more promising approach to understanding patient compliance behaviors has concentrated on a set of health

belief variables. This Health Belief Model (HBM) seeks to explain the way in which an individual chooses among alternative health actions (i.e., the decision to comply or not comply); it postulates that an individual's decision to take action relative to a particular health threat is a function of his/her beliefs along the following subjective dimensions: 1) beliefs about the nature of the health threat, in terms of personal susceptibility to that danger and its perceived severity if it should occur; 2) beliefs that specific actions, such as staying on a diet or taking medications as prescribed, will prevent or reduce the threat; and 3) beliefs about the barriers or costs that may be associated with taking the recommended action. Compliance is seen as more likely in patients for whom, in the presence of a perceived threat, the recommended action is viewed as beneficial and possible at a tolerable cost. It is important to note that the emphasis is on what the individual believes, rather than on what is held to be scientifically correct.

There is considerable research evidence that supports the usefulness of the HBM in accounting for variation in the extent to which people follow preventive practices,¹⁷ deal with symptoms¹⁸ and respond to illness.¹⁹ In a recent study by Hartman and Becker,¹⁵ the HBM was also used to predict dietary regimen adherence in a group of 50 hemodialysis patients; their findings indicated that, compared with noncompliers, compliers were more likely to: 1) view a list of sequelae commonly associated with noncompliance as having potential serious impact on life; 2) view the treatment as beneficial; and 3) report fewer difficulties in following the treatment regimen.

Besides health beliefs, other variables have been demonstrated to influence extent of compliance. Since recommendations for treatment vary in their demands on the patient (e.g., with regard to complexity and extent of required behavior

change), a number of studies have evaluated the characteristics of the regimen in relation to compliance.^{20,21} In general, the more the patient is told to do, the greater is the likelihood of noncompliance. Several studies have shown higher rates of medication errors (both overdosing and underdosing) when many doses of a medication are prescribed. The amount of change required by the health recommendation also seems to be related to compliance. In an investigation involving cardiac patients, Davis²² noted that patients tended to make those changes that required the least amount of adjustment for their lifestyle; modifications of personal habits, such as diet and alcohol consumption, were the least well followed.

Some knowledge of treatment instructions and of the reasons for the treatment also appear as important conditions for attaining acceptable levels of patient cooperation. Davis²³ found that when the significance of the regimen was not conveyed to patients, compliance suffered. In a study involving over 600 hemodialysis patients, Borkman¹¹ reported a significant association between patients' understanding of dietary restrictions and staff-rated dietary compliance. It is quite possible that the complexity of the regimen is related to compliance because of demands made on the patient's ability to comprehend, retain and apply details of the regimen.

Several studies have noted the important influence of support given by family members.^{12,15,16} Hartman and Becker¹⁵ found that hemodialysis patients who reported fewer family problems and received more assistance from their spouses (both in general and in health-related matters) complied better with a dietary regimen. In a study of 40 home hemodialysis patients, Pentecost et al.¹² reported that patients' compliance with their daily fluid restrictions was positively correlated with the quality of communication among family members. As a negative factor, social isolation

has been found to be related to noncompliance.¹⁰

A number of studies (including research on hemodialysis patients) point to the importance of patient-provider relationships. Kaplan-DeNour and Czaczkes²⁴ found an association between the expectations and evaluations of patients by dialysis clinic staff and subsequent patient compliance behaviors. Wertzel²⁶ reported a similar finding, showing that hemodialysis patients tended to conform to providers' expectations about their behavior.

The present investigation examines the relationships of health beliefs, knowledge about the treatment regimen, regimen complexity, family and provider support, and personal characteristics to compliance in a group of ambulatory hemodialysis patients. Adherence to three components of the treatment plan was examined: 1) taking phosphate-binding medicine; 2) following dietary restrictions (especially the limiting of foods high in potassium content); and 3) limiting fluid intake. Findings from this research effort are used to suggest ways for improving patient compliance.

Method

Setting and Subjects

The study was conducted in two outpatient dialysis clinics located in southeastern Michigan. Patients were accepted into the study if they had no unusual physical or mental disabilities that could be expected to interfere with their participation in an interview, were between 18 and 80 years of age, and had been receiving dialysis treatments for a minimum of three months. The eligible study group consisted of 120 patients (72 per cent of the total patient population from both clinics), each of whom received a letter briefly describing the research and asking him/her to participate. Interviews were conducted by trained interviewers while the patients were receiving their dialysis treatments at the clinics.

The interview included questions concerning the patient's treatment history (e.g., length of time receiving dialysis treatment, eligibility for kidney transplant); health beliefs; knowledge of the treatment regimen; perceptions about the amount of support received from family members, friends and clinic medical staff; personal characteristics; and self-reported compliance to components of the treatment regimen. Of the 120 potential study participants, only four refused to be interviewed ($n = 116$, 97 per cent cooperation rate).

Characteristics of patients at the two clinics were compared to determine the appropriateness of pooling data from both sites. Two-sample *t*-tests and chi-square analyses were performed on sociodemographic, medical history, health beliefs, and knowledge and social support variables, as well as on compliance levels. The analyses indicated no statistically significant difference at the $p < 0.10$ level between patients from the clinic sites. Thus, all subsequent analyses are based on combined data from the two clinics.

Patients ranged in age from 21 to 76 years (mean 54.8). Of the initial 116 study patients, 54 per cent were male, and half were white. The median level of formal education was high school graduation. Median family income was between \$10,000 and \$10,999 per year, with 16 per cent receiving less than \$5,000 annually. Most of the participants (67 per cent) were married, with 9 per cent never married and the remainder widowed, divorced or separated. Eight patients (7 per cent) reported that they lived alone. Fifteen per cent of the sample indicated that they were currently employed either full-time or part-time. Of those individuals not currently employed, 72 per cent indicated that they had stopped working because of their illness. The average length of time the study patients had been receiving dialysis treatments was 29 months; most patients (87 per cent) were

receiving dialysis treatments three times per week. Only a quarter of the patients ($n = 28$) indicated that they expected to have a kidney transplant in the future, and 14 patients (12 per cent) reported having received a kidney transplant.

Measures

Patient Compliance

Compliance with taking phosphate-binding medicine, with following dietary restrictions and with instructions for limiting fluid intake was measured using two methods of assessment: 1) information obtained from the patient's medical chart (i.e., blood chemistries and weight gains between dialysis treatment); and 2) patient self-report.

Medical Chart Information. Dialysis patients need to control the amount of phosphorus in their blood, since their kidneys can no longer perform this function adequately. Phosphate-binding medications are used to help control the amount of phosphorus that is absorbed in the intestinal tract. Thus, the serum phosphorus level (SPHL) is an indirect measure of patient compliance with taking phosphate-binding medicine. In this study, compliance with taking phosphate-binding medicine was assessed by averaging patients' SPHLs over a period of two to four months. In all, four measures were obtained, three taken before and one taken after the interview. For the great majority of patients, SPHLs were obtained routinely once every month.

Since patients with renal failure are unable to excrete potassium adequately, dietary restrictions are imposed to help the patient maintain proper levels of potassium in the blood. Thus, serum potassium level (SPL) is an indirect indicator of compliance with dietary restrictions of foods high in potassium (primarily fruits and vegetables). In this study, compliance with dietary restrictions was evaluated by averaging

patients' SPLs over a period of two to three weeks. Six measures were obtained, three before and three after the interview. SPLs were assessed routinely each time the patient came for dialysis.

To avoid excess fluid buildups, dialysis patients are restricted in the amount of fluid permitted between dialysis treatments. The degree of fluid restriction depends on patients' ability to excrete fluid on their own. Thus, interdialysis weight gain is an indirect measure of patient compliance with fluid restrictions. In this study, compliance with limiting fluid intake was appraised by averaging the patient's daily weight gains (DWGs) over a period of two to three weeks. The DWG was calculated by dividing the patient's between-dialysis weight gain by the number of days since the last dialysis treatment. Between-dialysis weight gains were calculated by subtracting from each patient's predialysis weight the previous treatment's postdialysis weight. Predialysis and post dialysis weights were obtained routinely at each treatment session.

As measures of compliance, the medical chart assessments have the advantage of being relatively unaffected by human judgments; however, these measures may not be accurate indicators of compliance since they can be affected by factors unrelated to patient compliance behavior. For example, both serum potassium and serum phosphorus levels can be influenced by the presence of a co-existing catabolic process or by the degree of adequacy of the dialysis treatment. Between-dialysis weight gains can be affected by patients' activity level, the number of calories in their diet and by the amount they perspire.

Patient Self-Reports. As part of the interview designed to assess health beliefs and knowledge about their illness, patients were asked to rate the degree to which they usually comply with instructions about their phosphate-binding medicine, their diet and their between-dialysis fluid limit.

Patients rated the direction and degree of their compliance with each of the three components of the medical regimen on a 7-point rating scale, where responses ranged from "poor" to "excellent" compliance.

While fairly direct, patient reports of behaviors are subject to several sources of potential invalidity, for example, the natural desire to report "good" behaviors and the difficulty of recalling instances of noncompliance. In general, studies that have compared self-reported compliance with other methods of measuring regimen compliance (e.g., physiologic measures such as blood samples and urine tests to detect trace levels of medication, pill counts, health outcomes) have found that patients tend to overestimate their compliance with recommendations.^{26, 27}

Health Beliefs

Items pertaining to particular health belief dimensions were combined into indices on the basis of content and interitem relationships. The major indices included: 1) perceived susceptibility to the sequelae of noncompliance with taking: phosphate-binding medicine (e.g., "What chance do you think there is that you would develop bone disease?"); dietary restrictions (e.g., "What chance do you think there is that you would have weak and tired muscles?"); and fluid intake limits (e.g., "What chance do you think there is that you would have shortness of breath?"); 2) perceived severity of sequelae associated with noncompliance with: taking phosphate-binding medicine (e.g., "How serious do you think it would be if you were to get high levels of phosphorus in your blood?"); dietary restrictions (e.g., "How serious do you think it would be if you were to get high levels of potassium in your blood?"); and fluid intake limits (e.g., "How serious do you think it would be if you were to store up too much fluid in your

body between dialysis treatments?"); 3) beliefs about the likely benefits of: taking phosphate-binding medicine (e.g., "How much do you think the phosphorus medicine helps to prevent you from developing bone disease?"); the diet (e.g., "How much do you think the diet helps you to prevent you from becoming weak and tired?"); and the fluid limit (e.g., "How much do you think limiting the amount of fluid you drink prevents you from having shortness of breath?"); 4) perceived barriers to: taking the phosphate-binding medicine as prescribed (e.g., "Did you ever miss taking your phosphorus medicine because the medicine was costing you a lot of money?"); following the diet (e.g., "Did you ever not follow the diet because you don't always have time to prepare special meals?"); and limiting fluid intake (e.g., "Did you ever not stick to your fluid limit because you felt the fluid limit was too strict?").

The susceptibility, severity and benefit items were measured using 7-point rating scales. Indices were constructed by computing mean scores. Estimates of internal consistency for these indices ranged from 0.57 to 0.92, with the indices of perceived severity and perceived benefits yielding the lowest and highest levels of consistency, respectively. The "barriers" items were coded either "yes" or "no"; these indices were constructed by adding the number of "yes" responses to items that assess factors interfering with a patient's compliance to a particular regimen (i.e., seven items concerning barriers to compliance with taking phosphate-binding medicine and to following dietary restrictions, and five items involving barriers to compliance with fluid restrictions).

Knowledge of Regimen Purpose

The patient's knowledge of how each of the regimen's three components is supposed to help was gauged by having two nurses (one from each clinic) rate each pa-

tient's response to three open-ended questions: 1) "How does the phosphorus medicine help you?" 2) "How does the diet help you?" and 3) "How does the fluid limit help you?" The nurses' ratings were scaled from "1" (does not understand purpose of treatment regimen) to "7" (understands exactly). The nurse raters were blinded with regard to which responses corresponded to which patients. The interjudge reliabilities for the three knowledge measures ranged from 0.65 to 0.70.

Knowledge of Treatment Instructions

To assess understanding of the limits imposed by the special diet, the dietitian in each clinic rated the patients' responses to the question: "What types of foods are restricted in your diet?" The dietitian's rating was scaled from "1" (not knowledgeable about types of foods restricted) to "7" (very knowledgeable). In judging a patient's response, the dietitians were instructed to consider both the accuracy and completeness of the answers.

Dietitians in each clinic were also asked to score their patients' responses to the question: "What is your daily fluid limit?" ("1" = correct, "2" = incorrect, which included "don't know"). Patients' knowledge of treatment instructions for taking phosphate-binding medicine was not assessed.

Regimen Complexity

A measure of regimen complexity relative to the taking of phosphate-binding medicine was constructed by multiplying the patient's report of the frequency of taking the medicine by the reported dosage of the medicine taken each time. Regimen complexity was not assessed for the diet and fluid intake restrictions.

Support From Family and Friends

A three-item index measured the extent to which the patients perceived their

spouse, other family members and friends as making it easier for them to do what they are supposed to do for their kidney disease. Items employed 7-point rating scales, and the index was constructed by computing the mean for the three items (internal consistency for the index was 0.65).

Support From Medical Staff

A two-item index measured the degree to which the patients viewed their doctors and other members of the dialysis staff as making it easier for them to follow their regimens. Again, items used 7-point rating scales, and the index was the mean for the two items (internal consistency for the index was 0.95).

Family Problems

A five-item index was constructed to represent the effects of the patient's illness on family life. Items included questions concerning the extent to which patients viewed their illness as: 1) interfering with the amount of time they spent with their spouse; 2) causing problems with their marriage; 3) creating financial problems for their family; 4) interfering with their role as a parent; and 5) causing other problems in their family life. All responses were obtained along 7-point rating scales, and an index was constructed by computing the mean for the five items (internal consistency for the index was 0.82).

Table 1 presents the means, ranges, and standard deviations for the compliance

TABLE 1. Means, Ranges, Standard Deviations and Number of Respondents for Compliance Measures and Independent Variables

Measure	N	Range	Mean	Standard Deviation
Compliance				
Phosphorus level (mg/dl)	101	2.40-10.1	5.84	1.34
Potassium level (mEq/L)	111	3.50-6.20	4.85	0.55
Daily weight gain (kilograms)	111	0.33-2.61	1.34	0.48
Patient's report of compliance with taking phosphate-binding medicine	98	1-7	6.02	1.21
Patient's report of compliance with dietary restrictions	111	1-7	4.88	1.46
Patient's report of compliance with limiting fluid intake	100	1-7	5.00	1.41
Independent Variables				
Perceived susceptibility to sequelae of noncompliance with taking phosphate-binding medicine	101	2-7	5.50	1.10
Perceived susceptibility to sequelae of noncompliance with dietary restrictions	111	3-7	5.64	0.92
Perceived susceptibility to sequelae of noncompliance with limiting fluid intake	108	3-7	5.97	0.92
Perceived severity of sequelae of noncompliance with taking phosphate-binding medicine	101	2-7	5.92	1.20
Perceived severity of sequelae of noncompliance with dietary restrictions	111	2-7	5.61	1.08

TABLE 1. Continued

Measure	N	Range	Mean	Standard Deviation
Perceived severity of sequelae of noncompliance with limiting fluid intake	108	4-7	6.12	0.84
Beliefs about benefits of taking phosphate-binding medicine	98	2-7	6.20	1.01
Beliefs about the benefits of the diet	111	3-7	5.81	1.04
Beliefs about the benefits of limiting fluid intake	108	3-7	6.00	0.89
Barriers associated with taking phosphate-binding medicine	101	0-6	1.93	1.57
Barriers associated with following dietary restrictions	111	0-7	2.82	1.68
Barriers associated with limiting fluid intake	108	0-5	1.74	1.28
Knowledge of how the phosphate-binding medicine helps	98	1-7	2.58	1.74
Knowledge of how the diet helps	111	1-6	2.80	1.39
Knowledge of how the fluid limit helps	102	1-6	3.51	1.27
Knowledge of foods restricted in the diet	111	1-7	4.51	1.32
Knowledge of daily fluid intake	108	1-2	1.62	0.49
Complexity of the phosphate-binding medicine regimen	96	1-16	5.45	3.63
Support from family and friends	114	1-7	5.52	1.56
Support from the medical staff	115	1-7	6.34	1.11
Family problems	93	1-7	5.12	1.75

measures and for each of the independent variables.

Results

Using the criterion compliance level set by the medical staff (an average SPHL of less than 5.5 mg/dl), only 30 per cent of the patients were found to be taking the phosphate-binding medicine appropriately. However, based on a compliance criterion level of an average SPL of less than 5.5 mEq/L, 86 per cent of the patients appeared to be following their dietary restrictions. Finally, using an average weight gain of

less than 3.0 kg between dialysis treatments as a criterion, 59 per cent of the patients could be classified as compliant in limiting their fluid intake.

According to the patient report measures of adherence, patients are most compliant with following instructions for taking their phosphate-binding medicine and least compliant with staying on their diet. The medical chart and patient report measures of compliance were weakly correlated (compliance with taking phosphate-binding medicine, $r = 0.36$; compliance with dietary restrictions, $r = 0.17$; and compliance with limiting fluid intake, $r = 0.06$).

Correlates of Compliance

The product moment correlations of health belief measures, knowledge measures, regimen complexity and social support measures with the measures of compliance are presented in Table 2.

The magnitude (and, in some cases, the direction) of the correlations varies depending on the method used to measure compliance. Patients' beliefs about the benefits of the phosphate-binding medicine are significantly correlated with both self-reported compliance with taking the medicine and with SPHL. Beliefs about the benefits of the diet are strongly correlated with the patient's reported compliance with the diet and moderately correlated with the patient's SPL. Beliefs about the benefits of limiting fluid intake are significantly related to self-reported compliance with limiting fluid intake, but are unrelated to the patient's DWG. The number of barriers reported by the patient as interfering with his/her ability to comply with the treatment regimen is significantly and negatively correlated with each of the three patient-reported measures of compliance and with the patient's SPL and DWG (i.e., patients reporting fewer barriers were more compliant). The patient's perception of the *severity* of sequelae that might result from noncompliance with the regimen was not associated with any of the compliance measures; however, perceptions about *susceptibility* to sequelae associated with not following a treatment regimen were positively and moderately correlated with self-reported compliance with dietary and fluid limits.

The patient's knowledge of the purpose of the treatment regimen is significantly related to SPHL but is not associated with self-reported compliance in taking the phosphate-binding medicine. Knowledge of the purpose of the treatment regimen is unrelated to both the patient report and medical chart measures of dietary and fluid limit compliance. It is of general interest to

note that 43 per cent of patients taking phosphate-binding medicine reported that they had no idea what the purpose of the medicine was; 24 per cent did not know the purpose of their diet, and 7 per cent did not know how their fluid restriction was supposed to help them.

Patients' knowledge of the types of foods restricted in their diets was not associated with dietary compliance, nor was knowledge about daily fluid limit related to keeping within daily fluid restrictions. Most patients (80 per cent) were fairly knowledgeable (i.e., were rated by the nutritionist at 4 or above on a 7-point knowledge scale) concerning the types of foods restricted in their diet. Eighteen per cent of the patients reported having no idea what their daily fluid limit was, and an additional 19 per cent reported their fluid limit incorrectly.

Complexity of the phosphate-binding medicine regimen (in terms of frequency and dosage schedule) is significantly correlated with the patient's SPHL (i.e., the more complex the regimen, the lower the compliance) but is unrelated to the patient's own reports about taking the medicine.

Measures of support from family members and friends are not related to any of the compliance measures. However, the patients' perception of the effects of their illness on their family life is significantly correlated with each of the three patient report measures of compliance and with the patient's DWG (i.e., the more patients see their illness as disrupting their family life, the poorer their compliance). Support from members of the medical staff at the clinic is moderately associated with the patients' reported compliance with taking their phosphate-binding medicine and staying on their diet.

Table 3 presents correlations of socio-demographic and medical history variables with measures of compliance with the three components of the treatment regimen. Again, the magnitude (and, in some cases, the direction) of the correlations de-

TABLE 2. Correlations (Pearson Product Moment) of Independent Variables and Compliance Measures

Independent Variables	Compliance Measures					
	Phosphorus Level (mg/dl) (SPHL)	Patient's Report of Compliance With Taking Phosphate-Binding Medicine	Potassium Level (mEq/L) (SPL)	Patient's Report of Compliance With Dietary Restrictions	Daily Weight Gain (Kilograms) (DWG)	Patient's Report of Compliance With Limiting Fluid Intake
Health Beliefs						
Perceived susceptibility to sequelae of non-compliance	-0.10 (101)	0.09 (98)	0.05 (111)	0.22* (111)	-0.08 (108)	0.17 (100)
Perceived severity of sequelae of non-compliance	0.05 (101)	0.18 (98)	0.09 (111)	0.09 (111)	0.01 (108)	0.03 (100)
Beliefs in the benefits of the regimen	0.21* (98)	0.37* (98)	0.15 (111)	0.56* (111)	-0.08 (98)	0.31* (100)
Barriers interfering with following the regimen	-0.14 (101)	-0.42* (98)	-0.24* (111)	-0.54* (111)	-0.26* (108)	-0.38* (100)
Knowledge						
Knowledge of the purpose of the regimen	0.22* (98)	0.02 (98)	-0.10 (111)	0.05 (111)	0.02 (99)	-0.07 (100)
Knowledge of treatment instructions	NM	NM	0.08 (111)	0.04 (111)	-0.10 (105)	0.01 (100)
Characteristics of the Regimen						
Regimen complexity	-0.35* (96)	0.01 (96)	NM	NM	NM	NM
Social Support						
Support from family and friends	-0.03 (100)	0.09 (97)	-0.01 (109)	0.10 (109)	-0.01 (106)	0.10 (98)
Support from the medical staff	0.07 (101)	0.20* (98)	0.12 (110)	0.25* (110)	-0.07 (107)	0.10 (99)
Family problems	-0.08 (83)	-0.35* (83)	-0.14 (88)	-0.27* (88)	-0.30* (86)	-0.27* (86)

Notes: N indicated in parentheses; NM = not measured.

* $p < 0.05$.

TABLE 3. Correlations (Pearson Product Moment) of Sociodemographic Variables, Medical History Variables and Compliance Measures

Independent Variables	Compliance Measures					
	Phosphorus Level (mg/dl) (SPHL)	Patient's Report of Compliance With Taking Phosphate-Binding Medicine	Potassium Level (mEq/L) (SPL)	Patient's Report of Compliance With Dietary Restrictions	Daily Weight Gain (Kilograms) (DWG)	Patient's Report of Compliance With Limiting Fluid Intake
Sociodemographic Variables						
Age (older patients are better compliers)	0.22* (101)	0.17 (98)	0.14 (110)	0.27* (110)	0.34* (110)	0.14 (99)
Sex (females are better compliers)	0.03 (101)	0.06 (98)	0.11 (111)	0.02 (111)	0.21* (108)	0.01 (100)
Family income	-0.04 (94)	-0.08 (91)	-0.01 (102)	0.06 (102)	0.06 (99)	0.11 (91)
Level of education	-0.11 (100)	-0.04 (97)	0.02 (110)	-0.08 (110)	-0.04 (107)	-0.06 (99)
Medical History Variables						
Length of time receiving dialysis treatments (the longer the time on dialysis the poorer the compliance levels)	-0.11 (101)	-0.03 (98)	-0.20* (111)	-0.11 (111)	-0.13 (108)	-0.04 (100)
Expect kidney transplant in the future (those who expect a transplant are poorer compliers)	-0.10 (94)	-0.17 (91)	-0.19* (102)	-0.19* (102)	-0.22* (99)	-0.02 (93)
Previous failed kidney transplant (those who have previously had a transplant are poorer compliers)	0.05 (101)	0.13 (98)	0.03 (111)	0.28* (111)	0.20* (108)	0.01 (100)

Note: N indicated in parentheses.

* $p < 0.05$.

depends on the method employed to assess compliance. Among the sociodemographic variables examined, only age is consistently associated with adherence; older patients tended to be somewhat better compliers. Using DWG measure as an indicator of compliance, findings show that females were more compliant with the fluid limit than were males.

With regard to medical history variables, the results reveal a modest, consistent, negative association between the length of time the patient has been receiving dialysis treatments and adherence; patients who have been on dialysis for a longer period of time tended to be poorer compliers. Patients' expectations about receiving a kidney transplant were significantly related to the patient report and medical chart measures of dietary compliance and to the patient's DWG. Patients who indicated that they expected to have a kidney transplant in the future were generally poorer compliers. The data also show failure of a previous kidney transplant to be associated with increased daily weight gains and with lower patient-reported compliance with the diet.

In addition to the bivariate correlations, multiple regressions were run on each dependent variable, utilizing the several psychosocial measures as predictors. For the three *self-report measures* (medication, diet and fluid limits), the results were consistent. In each case, beliefs about the benefits of the actions, beliefs regarding barriers to the actions and perceptions of family problems formed the set of significant predictors. Other measures, such as beliefs in susceptibility and severity, regimen complexity, social support, and so on, did not enter the regressions as significant contributors. The psychosocial factors accounted for between 30 per cent (fluid limit) and 53 per cent (dietary compliance) of the variation in the self-reported measures of adherence.

Medical chart information regarding adherence was much less consistently

predicted by the set of psychosocial factors. For SPHL, regimen complexity, perceptions of benefits and beliefs about susceptibility constituted the significant variables. For DWG, perceptions of barriers was a predictor, but so was age. Other measures yielded nonsignificant relationships, and, overall, 22 per cent of the variance was accounted for by the factors. For SPL, no measure yielded significant predictions, and only 13 per cent of the variance could be accounted for by the set of factors.

Discussion

Findings from this study suggest that patient compliance behavior is determined to a large extent by situational factors. For example, the most common barriers reported by patients as interfering with their attempts to stay on their diets included having a craving for foods not allowed in their diet (82 per cent), being away from home (61 per cent) and difficulty in preparing special meals (38 per cent). Difficulties frequently mentioned by patients as barriers in following fluid limit recommendations included getting thirsty (76 per cent) and problems with always having to measure the amount of fluid one can drink (43 per cent). Common problems in taking the phosphate-binding medicine included forgetting (58 per cent), being away from home (54 per cent) and having the prescription for the medicine expire (28 per cent). Complexity of the instructions for taking the phosphate-binding medicine was also associated with noncompliance. The results from the multiple regressions indicated that perceived barriers are significant predictors of most measures of compliance.

The assumption (proposed by HBM) that an individual decides to comply (or not comply) with a treatment regimen based on beliefs about probabilities of disease occurrence, severity of the disease should it occur, and likelihood of effective treat-

ment was generally not supported by these data. Examination of the mean scores on the health belief indices shows that the majority of patients perceived themselves to be susceptible to the sequelae of non-compliance, viewed the consequence of these sequelae as serious, and saw the treatment regimen as effective in preventing these sequelae from occurring. However, what patients *believe* they are doing or not doing is quite consistently related to beliefs regarding the efficacy and costs of the action.

Contrary to expectation, level of knowledge of treatment instructions was not associated with compliance. Perhaps the situational determinants of compliance override any effects that knowledge may have—or possibly the patient's ability to rely on family members to insure that they follow their regimen eliminates the need for exact knowledge of treatment instructions.

Knowledge of the purpose of the treatment regimen was found to be significantly related to compliance with taking phosphate-binding medicine, but unrelated to compliance with following dietary restrictions and with limiting fluid intake. In general, patients were not very knowledgeable about the purpose of their treatment regimen.

In contrast to several studies reported in literature,^{12, 15, 16} findings from this study showed little association between support given by family members and compliance. However, the extent to which patients viewed their illness as disruptive of their family life was related to compliance. Younger patients viewed their illness as causing more problems in family life than did older patients.

Practice Implications

Given this study's results, it is suggested that interventions aimed at improving the compliance behavior of hemodialysis patients should focus on reducing environ-

mental barriers that interfere with the patient's ability to comply. Thus, reducing the complexity of the schedule for taking the phosphate-binding medicine would appear to be one way to increase medication compliance. The use of dose dispensers and/or special reminders (such as stickers to put on the refrigerator) may be effective in helping patients to remember when to take the medicine. Having patients write out a menu for each meal a week or so in advance may be helpful in allowing them to plan some variety in the foods they eat and to help them in deciding what foods they need to purchase. Discussions with patients about the types of foods they can order when they eat in a restaurant may help them to stay on their diet when they are away from home. To help patients stay within their fluid limit, it may be useful to review the environmental cues commonly associated with consumption of fluids (e.g., cued by times of day, television watching, sitting alone, meal-times) and to develop strategies to manipulate these cues or to discuss alternative ways of reacting to the cues (e.g., eating hard candies to make saliva and help reduce dryness in the mouth). For patients who have difficulty pacing the amount of fluid they are allowed to have between dialysis treatments, one might suggest that the patient keep a container of water large enough to hold the total amount of fluid allowed in the refrigerator; they would either drink only from the container or remove an equivalent amount of water from the jug, thus allowing the patients to keep track of amount of fluid consumed between treatments.

The particular strategies used to improve compliance should always depend on the individual. However, the basic approach suggested involved analyzing the environmental factors likely to interfere with compliance behavior and rearranging the environment to facilitate the occurrence of the desired behavior. Different aspects of compliance are virtually unre-

lated, however, so that it is necessary to deal with each behavior in its own right. Furthermore, the results suggest that patients form quite definite assessments of how they are doing—judgments that may not correspond to “objective” measures. Practically speaking, it appears that multiple assessments of compliance, using a variety of measurement approaches, are the best way to assure accuracy in gauging levels of compliance.

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Knowledge, Attitude, and Compliance Dimensions of Antibiotic Therapy With PPIs

A Community Pharmacy-Based Study

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This pilot project was conducted to measure the effectiveness of patient package inserts (PPIs) when controlled interventions by pharmacists are increased. The PPIs were designed to be easily understood by patients and included information on possible side effects, interactions, compliance and instructions on how to take the medication. PPIs for penicillin and ampicillin were evaluated. Data analysis yielded the following results for respondents receiving PPIs, as compared with those who did not:

- Satisfaction with the amount of drug information received;
- Increase in knowledge concerning the drug's proper use;
- Higher rates of compliance;
- High rating given to the "helpfulness" of the PPI information;
- Interest in receiving PPIs routinely, particularly with new prescriptions.

The PPIs developed for this study were found to be valuable tools to respondents for understanding how to take their medications, both in terms of knowledge and behavior. Verbal reinforcement of the PPI by the pharmacist was also found to be helpful.

PATIENT PACKAGE INSERTS (PPIs) are standardized monographs of information about a drug or drug class intended for users of prescription medicines. PPIs have provoked much controversy as to their rationale, benefits and drawbacks.¹ Opponents argue that a beneficial role in therapeutics for PPIs has not been demon-

strated by adequate testing. Further, they state that PPIs will probably not be read by patients and that, if they are read, PPIs may promote self-diagnosis and prescription drug interchange among patients; may produce suggestion-induced side effects and adverse reactions among susceptible patients; may frighten patients away from needed therapy regimens; and may increase the legal liability of the drug maker, prescriber and dispenser. Proponents argue that PPIs should accompany prescribed drugs dispensed to patients because the safe and effective use of such medications requires that patients be informed of their benefits, risks and directions for use; furthermore, patients have a basic right to such information.

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The amount of information that may be included creates two categories of PPIs. *Full disclosure* PPIs present complete benefit-risk information and appear particularly useful with potentially hazardous "elective" drugs. A clear discussion of the existence of less hazardous and even less effective alternatives to therapy with such drugs in full-disclosure PPIs could help the patient, in consultation with the prescriber, to make a better educated benefit-risk decision about the course of treatment. *Selective disclosure* PPIs, on the other hand, give the patient basic information specifically aimed at ensuring that the prescribed medication is taken with optimal safety and therapeutic effect.

Green and Faden² have estimated that it is highly likely that well-designed PPIs will increase patients' awareness of drug information, aid patients' comprehension and recall of drug information, help patients recognize side effects, and improve patients' confidence and competence in self-care. They have estimated that it is moderately likely that such PPIs will increase patients' interest in drug information, enhance patients' informed consent, reduce patients' errors in dosage and dosage omissions, increase patients' reporting of side effects and decrease the fear of side effects among patients. Enhanced compliance with certain therapy regimens, especially those prescribing antibiotics, through reduction of dosage and omission errors, has also been demonstrated with PPIs.¹

Methods to increase compliance with prescribed drug regimens are needed. Studies have found varying, but in all cases high, rates of noncompliance with drug therapy regimens. One study reports noncompliance ranging from 20 to 82 per cent³; another found noncompliance at 35 per cent.⁴ A review of the literature on noncompliance states that it reaches as high as 60 per cent in some groups.⁵ Broadly conceived, noncompliance includes omis-

sions of scheduled doses, premature cessation of therapy, administration errors such as instilling suspensions for oral use into the ear, timing errors, overutilization and utilization with medicinal agents not intended by the prescriber.

Providing counseling alone, without written instruction, has several shortcomings.⁶ The patient may forget or not even hear the information, due to stress and other factors. The physician may be too busy to provide sufficient information or explanation, or may be unaware of the information the patient needs. The patient may be discouraged from asking questions of the physician or the pharmacist. The prescription may be dispensed to a client other than the patient, with a possible loss of information in the transfer. In addition, the patient may receive the prescription in the pharmacy from a nonpharmacist not trained in counseling patients about prescription drugs.

Yet while counseling alone has its drawbacks, written information alone, without verbal counseling, has also shown a negative effect on compliance.⁷ This points to the hypothesis that a combination of written and oral instruction would be a more effective way to convey drug information to patients.

To test this hypothesis, we have adapted a widely used model in health education that measures an educational tool or process according to its effect on patient *knowledge, attitudes and behavior*. The thesis underlying this model is that given adequate and understandable information, a patient should become more knowledgeable about his/her medical condition and its treatment. With increased knowledge, a change in attitude would be anticipated, disposing the patient to cooperate with the treatment regimen. Finally, as a result of the positive changes in knowledge and attitudes, the patient is more likely to adopt behaviors that will lead to improved health. In the case of drug therapy regi-

mens, the desired behavior is compliance. Ideally, then, according to the health education model, a well-designed and comprehensible PPI, combined with a planned verbal consultation, should augment patient knowledge, leading to an attitude of cooperation with the physician and pharmacist, which should result in improved adherence to the medication regimen.

Description of the Study

The study was supported in part by a grant from the Hunterdon Health Fund and was conducted by the Office of Consumer Health Education of the Department of Environmental and Community Medicine, Rutgers Medical School, College of Medicine and Dentistry of New Jersey, in collaboration with the Department of Pharmacy Administration, College of Pharmacy, Rutgers University.

This study was designed as a pilot study in preparation for a statewide study that would randomly assign the study population to various educational interventions at different types of pharmacies. As a pilot study, the principal objective of this study was to evaluate the effects of PPIs on the knowledge, attitudes and compliance of patients on a short course of therapy with either penicillin V, penicillin G or ampicillin. The quasi-experimental research design included three sequential levels of educational intervention, requiring an increasing amount of involvement by the pharmacist. The participating pharmacists were trained in their role just before each intervention was to begin in order to control for pharmacist bias toward one intervention. The pharmacists knew that their role in the study would change but did not know until each intervention began the scope of their role for the specific interventions. In addition to the training for each educational intervention, a printed reminder sheet highlighting their role for the specific educational intervention was hung at the dispensing counter.

Potential subjects were identified for each educational intervention at each study site and were not included in more than one educational intervention. The stages were as follows:

Educational Intervention I. The study drugs were dispensed to patients in this group with no planned educational intervention by the pharmacists. At dispensing, the pharmacists responded to any questions patients may have had but transmitted no further written or oral drug information. This intervention constitutes the control group for the study.

Educational Intervention II. The study drugs were dispensed with a PPI to patients during this intervention. The pharmacists responded to any questions patients may have had, as in Intervention I, and they dispensed the PPI as unobtrusively as possible, making no overt reference to it. Patients in Educational Intervention II thus received only the PPI, with no planned verbal reinforcement by the pharmacist.

Educational Intervention I. The study drugs were dispensed to patients in this group. In addition, patients received verbal counseling by the pharmacists, which included notifying them about the PPI, encouraging them to read it and highlighting its salient points. Thus, patients in Educational Intervention III received both the PPI and verbal consultation by the pharmacist.

Study Sites and Respondents

Two community pharmacies under the same management were selected as sites for the study. Although the pharmacies are both located in central New Jersey, one serves primarily an urban community and the other a more rural community.

Both sites have procedures for providing minimal patient counseling, which expedited the implementation of this study. In a follow-up study, it would be interesting to

include sites that do not normally provide patient counseling in order to determine if patient expectations vary according to past pharmacy practices.

Patients who presented with new prescriptions for the study drugs were given a consent form to read while their prescriptions were being prepared. The form explained that a telephone survey was to be conducted by the CMDNJ-Rutgers Medical School and the College of Pharmacy. Information collected would be treated confidentially and would be used for statistical purposes only. Patients could signify their agreement to participate in the survey by signing the forms and providing their telephone numbers. Pharmacists collected the forms from all patients to whom they had been given. Although data were not gathered on patients who refused to sign the consent form, according to the pharmacists, very few patients declined to participate. Care was taken throughout the recruitment procedure to avoid explaining the reasons for the survey or describing the study objectives.

Patients who signed the consent forms were called for the telephone interview not more than three days before their prescribed regimen should have been completed. For each educational intervention, a sample of 62 respondents was obtained before the next educational intervention was implemented. Although it would have strengthened this study to have randomly assigned patients to educational interventions in order to control for seasonal and similar variations, it was not possible since this study made use of only two pharmacy sites. Consequently, in order to control the educational interventions, it was necessary to complete one educational intervention for a group of patients before the next intervention was begun. This was necessary in order to ensure that a patient from Intervention I, for example, did not overhear the information being given to a patient in Intervention III who happened to be receiving the same prescriptions at the same

time. Simultaneous collection of data from the three intervention groups could be accomplished in a study with more sites in which the pharmacies and consequently the patients could be randomly assigned to different educational interventions. However, in this study it was not possible to collect data on all three educational intervention groups at the same time.

Respondents who were not available when first called were called again at a later time, but always before the prescribed regimen was due for completion. When data collection began in September 1978, the incidence of prescriptions for the study drugs was rather infrequent as compared with the last stage of data collection in late November and early December. Therefore, it took longer to assemble a sample of 62 respondents in Educational Intervention I than in Intervention II or Intervention III.

Interview Questionnaire

An interview questionnaire was developed with a minor modification that allowed it to be used both for patients who had and who had not received the PPI. The instrument included questions about what information respondents remembered receiving when their prescriptions were dispensed, their satisfaction with the information received and any further information they would have liked to receive. Respondents who reported receiving the PPI were asked if they had read it, if they had found it helpful, if they were satisfied with the amount of information it contained, if it was easy to read and if they would like PPIs dispensed routinely with prescription drugs. Respondents who reported receiving verbal counseling from the pharmacist were also asked if the consultation had been helpful, if they were satisfied with the amount of information presented by the pharmacist and if they would like the pharmacist to counsel them routinely when they have prescriptions dispensed.

Such questions may be taken as measures of attitude toward information received in the three educational interventions.

In an effort to keep the telephone interview time to a minimum, the pharmacy patient profile cards were used to collect data regarding the patient's sex and age. In a follow-up study, additional items such as years of education, family income, occupation and type of illness should be included in order to develop a more complete profile of respondents.

The instrument also asked respondents three questions probing their knowledge of the study drug prescribed. A final section dealt with medication-taking behavior and, as a measure of compliance, asked respondents to count the tablets or capsules, or to estimate the amount of liquid remaining to be taken at the time of interview.

The questionnaire was pretested during the month of August. As a result, it was edited slightly to improve language and the flow pattern of questions.

PPI Development

In determining the basic content to be included in the study PPIs for penicillin and ampicillin, the package inserts for those drugs, intended for health professionals, were used as source material. The most difficult and time-consuming aspects of the PPI design involved deciding what information to include for a *selective disclosure* PPI and simplifying complicated technical language for lay comprehension, while still providing adequate, useful information. A three-section format on one page was developed. The first (introductory) section identifies the drug by its generic and more common brand names, briefly explains the drug's actions and instructs the patient to report certain pre-existing conditions to the physician if he/she has not already done so. The second section contains instructions for taking the medication, and the third section presents

advice regarding side effects, storage of the medication and general precautions. The PPIs developed for this study appear in the Appendix.

Results and Discussion

Forty-four per cent of the 186 study participants were males. The percentage of males tended to increase from Interventions I to III (36 per cent were males in Intervention I, 46 per cent in II, and 51 per cent in III). Both children and adults received the study drugs; however, if a patient was under 16 years of age, the parent was contacted for the interview. Nearly twice as many patients received prescriptions for penicillin (66 per cent) as for ampicillin (34 per cent). Intervention I showed a larger number of ampicillin prescriptions (29) than did Intervention II (18) or III (17). All of the prescriptions were for oral dosage forms of the study drugs, with 26 per cent of the patients receiving liquid preparations and 74 per cent receiving capsules or tablets. Therapy regimens of less than ten days were prescribed for 52 per cent of the patients, while ten-day regimens were prescribed for 46 per cent. Only 2 per cent of patients received prescriptions for therapy regimens longer than ten days. The length of regimen did not vary appreciably among the three interventions.

Most respondents accurately described the intervention to which they had been exposed. Fifty-eight per cent of the respondents in Educational Intervention I reported receiving neither written nor verbal instructions when they obtained their prescribed medications. Eighty-two per cent of respondents in Intervention II were aware that they had received a PPI with their antibiotic. In Educational Intervention III, 94 per cent of respondents were aware of receiving a PPI, and 89 per cent reported having received verbal consultation from the pharmacist as well (Table 1).

TABLE 1. Respondents' Awareness and Use of PPI by Type of Educational Intervention

Awareness and Use	Educational Intervention* (Per Cent of Total)		
	II	III	II and III Combined
Aware PPI Received	82 (N = 62)	94 (N = 62)	88 (N = 124)
Read PPI	96 (N = 51)	91 (N = 58)	94 (N = 109)

* Educational Interventions:

- I. Study drugs dispensed to patients with no planned educational intervention.
- II. Study drugs dispensed to patients with a PPI.
- III. Study drugs dispensed to patients with a PPI and reinforced with verbal counseling by the pharmacist.

It should be noted that the pharmacist's verbal reinforcement in Intervention III significantly increased the proportion of respondents who were aware of the PPI over the proportion of respondents aware of the PPI in Intervention II ($Z = 1.97$, $p < 0.05$).

Factors that explain why respondents reported receiving verbal and/or written instructions from the pharmacist inappropriate to the planned educational intervention include: random deviations from the design of the interventions by the pharmacists during the study*; the limitations of the survey instrument; and the dispensing practices ordinarily followed in both study pharmacies. For example, the survey instrument did not specify exactly what was meant by "instructions" received at the time of dispensing. This ambiguity might easily have caused respondents to interpret the typed directions on the prescription container as "written instructions," or the pharmacist's response to questions asked at the time of dispensing as "verbal instructions." Also, as a standard dispensing practice at the study pharmacies, pharmacists routinely counsel patients at a

separate, semiprivate section of the transaction counter marked "For Prescriptions Only" and, as needed, provide prescription patients with a printed checklist of special instructions (Fig. 1). Respondents accustomed to such verbal and written instructions could easily have reported receiving them, even though they were not provided during the study. Clearly, however, only respondents in Interventions II and III actually received the study PPIs, and only respondents in Intervention III received the pharmacist-initiated, verbal consultation regarding the PPI and its contents.

Information Desired

As illustrated in Table 2, 63 per cent of the respondents in Intervention I reported wanting more information about their prescriptions than had been received. This group includes 79 per cent of those Intervention I respondents who reported receiving no information of any kind and 42 per cent of those who reported receiving some information. These respondents desired a wide range of information including: the drug's potential for interaction with other drugs and alcohol (31 per cent); specific dosing instructions, such as whether to administer the drug around the clock, during waking hours only or at meal-times (29 per cent); any special instructions or precautions that should be followed dur-

* The incidence of such deviations was probably minimal, since the pharmacists appeared genuinely interested in participating in the study, received training in the parameters of their role only before each intervention, and were given printed reminder sheets for the dispensing counter for each intervention so as to reduce confusion.

PATIENT'S NAME _____	
PREScription NUMBER _____	
PHARMACIST'S INSTRUCTIONS	
IF THERE ARE ANY QUESTIONS, PLEASE ASK OUR PHARMACIST	
Take every hours times a day (doses today)	
Take the medication until gone. (days)	
Take as needed only.	
Take continuously.	
Continue during menstrual period.	
Take with a full glass of water.	
Take on empty stomach (1 hr. before or 2 hrs. after meals)	
Do not use milk, dairy products, iron, or antacids within 1 hour.	
Take on full stomach (during or immediately after meals or with milk or snack).	
Take before 10 A.M.	
May cause drowsiness.	
Do not drive or operate machinery if drowsiness occurs.	
Do not use alcoholic beverages.	
Do not use antihistamines or cold preparations.	
May use aspirin or acetaminophen (Tylenol) at same time.	
Do not use aspirin or aspirin containing compounds.	
May discolor urine.	
Apply sparingly, rub in well.	
Avoid excessive sunlight.	
Do not take _____ at same time	
May take _____ at same time	
May take _____ at same time, but drowsiness may occur.	

These instructions are provided to you as a service by:

FIG. 1. Printed Checklist of Special Instructions. As a standard dispensing practice at the study pharmacies, pharmacists may provide patients with this checklist. During the study this form was not used for Educational Interventions I, II or III.

ing therapy (17 per cent); side effects (17 per cent); and the drug's name, expiration date and indications for use (6 per cent).

In contrast, only 18 per cent of the respondents in Educational Intervention II and 14 per cent of those in Intervention III reported a desire for more information than they received (Table 2). The difference between the proportion of respondents in Intervention I who wanted more information and the proportion in Interventions II and III combined was found to be highly significant ($Z = 6.37, p < 0.01$). This indicates

that providing patients with a PPI or a PPI with verbal consultation by the pharmacist significantly reduced their desire for more information about the prescribed drug. The difference between respondents in Interventions II and III who wanted more information is small and could be due to chance.

Of those respondents in Intervention II who reported receiving as well as reading the PPI, 6 per cent wanted additional information, while only 4 per cent of Intervention III respondents who reported

receiving and reading the PPI as well as receiving the pharmacist's consultation wanted additional information. These data increase the significance of the difference between Intervention I and Interventions II and III combined regarding the proportion of respondents who desired more information about their prescribed drug ($Z = 7.88$, $p < 0.01$). Once again, the difference in the proportion of respondents desiring more information in Interventions II and III is small and could be due to chance (Table 2).

Respondents who reported experiencing Interventions II and III as planned but who still wanted more information said they wanted to know: what specific infections the drug is used to treat; how best to administer the liquid dosage forms to an uncooperative child; the potential for food-drug interactions; and the manifestations of severe, allergic reactions to the drug.

Knowledge Measures

In addition to satisfaction items regarding the PPI and the pharmacist's verbal role, the interview included the following knowledge items:

1. Should you take this medicine if you are allergic to penicillin?

2. Is it necessary to take all the antibiotic even though you feel better before it is finished?

3. Should this antibiotic be taken with meals?

Respondents who had received the PPI alone (Intervention II) or with verbal counseling by the pharmacist (Intervention III) answered these questions correctly more often than did respondents who had received neither (Intervention I). In addition, although not statistically significant, there was a tendency for knowledge responses to increase in accuracy as the educational intervention increased from I to III.

In response to the first question, 79 per cent of Intervention I respondents answered correctly that the study drugs should not be taken by persons allergic to penicillin (Table 3). This percentage rose to 97 per cent in both Interventions II and III. The difference is significant ($Z = 3.89$, $p < 0.01$) and indicates that providing respondents with a PPI alone or with verbal consultation by the pharmacist significantly increased their correct responses to this item.

The necessity for completing the therapy regimen was known by 85 per cent of the respondents in Intervention I, 87 per cent of respondents in Intervention II and

TABLE 2. Per Cent of Respondents Desiring More Drug Information Than Received by Type of Educational Intervention

Desire More Information	Educational Intervention* (Per Cent of Total)		
	I	II	III
Total group	63 (N = 60)†	18 (N = 62)	14 (N = 62)
Adjusted group‡	63 (N = 60)†	6 (N = 49)§	4 (N = 48)¶

* See Table 1 for a description of the Educational Interventions.

† Excludes two nonrespondents.

‡ Includes respondents who reported receiving Educational Interventions II and III as planned.

§ Excludes 11 respondents who reported not receiving the PPI and two who reported not reading the PPI.

¶ Excludes five respondents who reported not receiving the PPI, five who reported not reading the PPI and four who reported not receiving the pharmacist's consultation.

TABLE 3. Per Cent of Correct Responses* to Knowledge Items by Type of Educational Intervention

Knowledge Items	Educational Intervention †		
	I	II	III
1. Should take medication if allergic to penicillin?	79	97	97
2. Necessary to take the total prescription?	85	87	92
3. Should take medication with meals?	33	87	89
Total knowledge items	66	90	93

* The denominator for Intervention I excludes one nonrespondent but is 62 for Interventions II and III.

† See Table 1 for a description of the Educational Interventions.

92 per cent of respondents in Intervention III. These differences are small and could be explained as occurring at random in this study.

When asked whether the study drugs should be taken with meals, only 33 per cent of respondents in Intervention I knew that the antibiotics are best administered on an empty stomach (Table 3). By contrast, 87 per cent of the respondents in Intervention II and 89 per cent of the respondents in Intervention III responded to this question correctly. The difference between the proportion of respondents who correctly answered this question in Intervention I and in Interventions II and III combined was found to be highly significant ($Z = 7.57$, $p < 0.01$), which indicates that providing respondents with a PPI alone or with verbal consultation by the pharmacist significantly increased their knowledge regarding this item. Here too, the difference between the proportion of correct responses in Interventions II and III is small and could be explained as occurring by chance.

Attitude Measures

The PPIs enjoyed wide readership and elicited favorable comments by most respondents who received them. Ninety-four

per cent of those who reported receiving PPIs also reported reading them. This group includes 96 per cent of the respondents in Intervention II and 91 per cent of the respondents in Intervention III (Table 1). In both interventions, 90 per cent of those who reported receiving and reading the PPI rated its helpfulness positively—64 per cent rating it "very helpful" and 26 per cent "somewhat helpful" in understanding how to take the medication (Table 4). Furthermore, 95 per cent of the respondents who reported receiving and reading the PPI reported satisfaction with the amount of information it contained. All respondents who reported receiving as well as reading the PPI rated its readability positively—90 per cent describing the PPI as "very easy to read" and 10 per cent as "somewhat easy to read." In addition, 99 per cent of the respondents in Educational Interventions II and III who reported that they had received and read the PPI said that they wanted written drug information with other prescriptions. This group includes 98 per cent of the respondents in Intervention II and all the respondents in Intervention III who reported receiving and reading the PPI.

The verbal consultation provided by the pharmacist was also well received by the

TABLE 4. Respondents Reporting Positive Attitudes Regarding PPI by Type of Educational Intervention

Attitude	Educational Intervention* (Per Cent of Total)†		
	II	III	II and III Combined
Helpfulness of PPI	90	91	90
Completeness of PPI	94	96	95
Readability of PPI	100	100	100
Desire PPIs for other prescriptions	98	100	99

*See Table 1 for a description of the Educational Interventions.

†Based on only those respondents who reported reading the PPI: 49 for Intervention II and 53 for Intervention III.

respondents in Intervention III (Table 5). Of those who reported receiving the pharmacist's counseling, 89 per cent found it "very helpful" and 11 per cent "somewhat helpful" in understanding how to take the study drugs. This same group was unanimous in reporting satisfaction with the amount of information received from the pharmacist. Ninety-eight per cent reported that they would like the pharmacist's verbal consultation each time they had a prescription dispensed; 2 per cent would restrict the consultation to new prescriptions only.

Compliance Measures

Behavior in each of the three educational interventions was explored by examining respondents' compliance with the therapy regimen. During the telephone interview, respondents were asked to count the number of doses remaining in their medication containers, as a way of gauging their adherence to the therapy regimen. Since it soon became apparent that respondents who were taking or administering liquid dosage forms could not, by their own admission, reliably estimate the volume of liquid or the number of teaspoonfuls remaining in the bottle, the study of compliance was limited to the 74 per cent of respondents (N = 137) who were taking or administering either tablets or capsules.

During the course of the telephone interview, 95 per cent of these 137 respondents agreed to count the number of tablets or capsules remaining in their containers.

Information regarding the beginning date of therapy, the number of days' supply of drug, the daily dosage schedule, and the total number of doses prescribed was available from each respondent's prescription. In each case, the determination of compliance or noncompliance involved comparing the pill count, as reported by the respondent, with the number of doses that should have been in the container if the therapy regimen had been followed correctly up to the date of interview. Non-

TABLE 5. Respondents Reporting Positive Attitudes Regarding the Pharmacist's Verbal Consultation Provided in Intervention III

Attitude	Educational Intervention III* (Per Cent of Total)†
Helpfulness of counseling	100
Completeness of counseling	100
Desire for counseling with other prescriptions	98

* See Table 1 for a description of Educational Intervention III.

†Based on only the 55 respondents in Intervention III who reported receiving counseling; these 55 represent 89 per cent of the 62 respondents who should have received it.

compliance was defined as overutilization or underutilization of the study drugs by the date of the telephone interview.

Overutilization. If the pill count showed fewer doses remaining in the prescription container than there should have been by the end of the interview day, the respondent was classified as noncompliant by virtue of overutilization. For example, a pill count of ten unconsumed doses on the evening of the sixth day of a 30-dose regimen (i.e., a ten-day, three-times-daily therapy) would be classified as overutilization, since no more than 18 doses should have been consumed by the end of the sixth day. This would leave 12 capsules to be consumed during the last four days, instead of ten.†

Underutilization. If the pill count showed that more doses remained in the prescription container than there would have been had the regimen been followed correctly, a different calculation was used to classify the respondent as noncompliant by virtue of underutilization. Not knowing exactly when the therapy should have been initiated, or the time of day when the prescription had been dispensed, the assumption was made that the respondent might still be in compliance with the regimen even if only the last of the first day's required doses was administered. It was further assumed that the last dose of the day could have been scheduled for administration after the time of the telephone interview. For example, a pill count of 15 unconsumed doses on the evening of the seventh day of a ten-day, four-times-daily therapy (40 doses prescribed) could not be classified as underutilization, since the patient might have consumed one dose on the first day of therapy, 20 doses over the next five days and three doses on the interview date up to the time of the interview, for a total of 24 doses consumed. A pill count of

† Overutilization may thus be stated as $P < N - df$, where P = the self-reported pill count; N = the number of doses prescribed; d = the day of therapy on which the interview date falls; f = the daily dosing schedule.

up to 16 unconsumed doses at the time of interview could be considered compliant behavior in this case, while a pill count of 17 or more unconsumed doses would require classification as underutilization.‡

Compliance. Using these definitions to determine compliant and noncompliant behavior, analysis shows that 48 per cent of the respondents in Educational Intervention I complied with the therapy regimen (Table 6). The percentage increased to 57 per cent in Intervention II and to 72 per cent in Intervention III.

Although the differences between the percentages of compliant respondents in Interventions I and II, and Interventions II and III, were found not to be statistically significant, there was a tendency for compliance to increase as the rates of educational intervention increased from I to III. The difference between the percentage of compliant respondents in Interventions I and III was found to be significant ($Z = 2.22$, $p < 0.05$) and indicates that compliance increased among respondents who received both a PPI and consultation by the pharmacist, when compared with those who received neither intervention.

Conclusions

The study has demonstrated that patients who lack substantive information about the drugs prescribed for them desire more drug information. Only 37 per cent of the respondents who had prescriptions dispensed with neither a PPI nor planned verbal intervention by the pharmacist were satisfied with those conditions. In the study, respondents perceived the adequacy of the information they received along a kind of continuum, as follows:

‡ Underutilization may be stated as:
 $P > N - (df - 4)$ for four-times-daily regimens.
 $P > N - (df - 3)$ for three-times-daily regimens.
 $P > N - (df - 2)$ for twice-daily regimens;
 where P = the self-reported pill count; N = the number of doses prescribed; d = the day of therapy on which the interview date falls; and f = the daily dosing schedule.

TABLE 6. Noncompliant Versus Compliant Behavior With Nonliquid Therapy Regimens by Type of Educational Intervention

Behavior Type	Educational Intervention*		
	I	II	III
Underutilization	13 (33%)	8 (18%)	6 (13%)
Overutilization	8 (20%)	11 (25%)	7 (15%)
Total noncompliance	21 (53%)	19 (43%)	13 (28%)
Total compliant	19 (48%)	25 (57%)	33 (72%)
Total respondents†	40 (101%)	44 (100%)	46 (100%)

* See Table 1 for a description of the Educational Interventions.

† Omits two nonrespondents in I, four in II and one in III who received nonliquid therapy regimens.

1. Among those who reported receiving and reading the PPI as well as receiving the pharmacist's consultation, 96 per cent did not desire additional drug information.

2. Among those who reported receiving and reading the PPI without the pharmacist's consultation, 94 per cent did not desire additional drug information.

3. Among those who reported receiving the PPI and the consultation of the pharmacist (includes those who may not have read the PPI), 86 per cent did not desire additional drug information.

4. Among those who reported receiving the PPI (includes those who may not have read it) without the pharmacist's consultation, 84 per cent did not desire additional drug information.

5. Among those who reported receiving less information in some form, 58 per cent did not desire additional drug information.

6. Among those who reported receiving no information, 21 per cent did not desire additional drug information.

It appears, therefore, that the communication of drug information through the medium of the PPI satisfies patients' desires for information about prescription drugs.

Although some have argued that patients will not read PPIs, this study has demonstrated that patients do read them. Ninety-four per cent of patients aware of the PPI in this study reported reading it. Awareness of the PPI was significantly greater among patients who received it with the pharma-

cist's consultation (94 per cent aware), though awareness was high (82 per cent) even among patients who received the PPI without reinforcement by the pharmacist.

The study found that knowledge of certain points of information concerning the prescribed drugs was more prevalent among respondents who received the PPI than among those who did not. For two of the three knowledge items, significantly greater numbers of respondents who received PPIs knew the correct answer. It appears, therefore, that PPIs designed with patients' needs in mind can increase their knowledge of prescription drug information.

This study proved to be no exception to the general finding that patients react favorably to PPIs. Ninety per cent or more of respondents who read the PPI reported that they found the information it contained helpful in explaining how to administer the study drugs, complete and readable, and would like to see PPIs dispensed with other prescription drugs. The same kind of enthusiasm has been reported previously in studies of women who received a PPI with oral contraceptives,^{8,9} although such women have shown rather disappointing knowledge of the PPI when questioned about its contents.^{9,10} It has been suggested that while patients respond favorably to being given PPIs, the reading sophistication required for easy

comprehension keeps many from completely understanding the information conveyed and explains why they cannot correctly answer questions about content.¹¹ The PPIs used in this study, therefore, were designed with care to enhance both usefulness and comprehensibility.

The study also found broad support for counseling by the pharmacist. The planned verbal consultation of Intervention III was well received by respondents; those who reported receiving the pharmacist's counseling were unanimous in rating the information conveyed as complete and helpful. Only one respondent did not want the pharmacist's advice given routinely with prescription drugs, and that person suggested having the pharmacist counsel only patients with new prescriptions and not those with refills. Moreover, the pharmacist's counseling was instrumental in increasing awareness of the PPI among patients.

The findings of the study also support the conclusion that PPIs can enhance patient compliance with prescribed antibiotic regimens. The results show that patients given PPIs and verbal reinforcement by the pharmacist have significantly greater compliance rates than patients who receive neither.

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Appendix

Penicillin

Your penicillin may be known by one of several brand names such as Bicillin®, Pentids®, Pen Vee K®, V-Cillin® or others.

Penicillin is an antibiotic used to treat infections caused by certain bacteria. As a rule, PERSONS WHO HAVE HAD AN ALLERGIC REACTION TO PENICILLIN SHOULD NOT TAKE IT AGAIN.

- If you are allergic to penicillin and have not told your doctor, tell him before starting penicillin. If you have a history of allergies to many things and have not told your doctor, tell him/her before starting penicillin.

How to Take Penicillin by Mouth

- Take *all* your penicillin. If the doctor orders a refill, you should *finish it all* too. Don't stop taking penicillin after a few days because you feel better. Continue taking it because the infection may still be in your body.
- Follow the instructions on the label and take every scheduled dose of penicillin with a glassful of water. **DON'T SKIP ANY DOSES.** If you have a question about the number of doses to take or the timing of each dose, ask your pharmacist.
- *Whenever possible* take each dose of penicillin on an empty stomach **ONE HOUR BEFORE OR TWO HOURS AFTER MEALS.** This is because food, fruit juices, or antacids like Gelusil®, Maalox®, Alka Seltzer®, etc. may slow down the effect of penicillin. When it's not possible or convenient to do this, take each dose of penicillin anyway. Remember, **DON'T SKIP ANY DOSES.**

Advice to Patients

- If you begin to have any problems while taking penicillin, such as itching, skin rash or hives, nausea, vomiting or diarrhea, call your doctor.
- Do not give any of this medicine to anyone else. Keep this and all medicines out of the reach of children.
- Penicillin tablets should be stored at room temperature away from excess moisture.
- Penicillin liquid, for teaspoonful or dropper dosage, should be stored in a refrigerator. Shake well before taking. After 14 days amounts not used should be thrown away (flushed).
- If you have any questions about penicillin, ask your doctor or pharmacist.

Ampicillin

Your ampicillin may be known by one of several brand names such as Polycillin®, Principen®, Penbritin® or others.

Ampicillin is an antibiotic used to treat infections caused by certain bacteria. Ampicillin is like penicillin. So, as a rule, **PERSONS ALLERGIC TO PENICILLIN SHOULD NOT TAKE AMPICILLIN.**

- If you are allergic to penicillin or ampicillin and have not told your doctor, tell him/her before starting ampicillin.

- If you are pregnant, or think you might be, and have not told your doctor, tell him/her before starting ampicillin.

How to Take Ampicillin by Mouth

- Take *all* your ampicillin. If the doctor orders a refill, you should *finish it all* too. Don't stop taking ampicillin after a few days because you feel better. Continue taking it because the infection may still be in your body.
- Follow the instructions on the label and take every scheduled dose of ampicillin with a glassful of water. **DON'T SKIP ANY DOSES.** If you have a question about the number of doses to take or the timing of each dose, ask your pharmacist.
- *Whenever possible* take each dose of ampicillin on an empty stomach **ONE HOUR BEFORE OR TWO HOURS AFTER MEALS.** This is because food, fruit juices, or antacids like Gelusil®, Maalox®, Alka Seltzer®, etc. may slow down the effect of ampicillin. When it's not possible or convenient to do this, take each dose of ampicillin anyway. Remember, **DON'T SKIP ANY DOSES.**

Advice to Patients

- If you begin to have any problems while taking ampicillin such as itching, skin rash or hives, nausea, vomiting or diarrhea, call your doctor.
- Do not give any of this medicine to anyone else. Keep this and all medicines out of the reach of children.
- Ampicillin capsules and tablets should be stored at room temperature away from excess moisture.
- Ampicillin liquid, for teaspoonful or dropper dosage, should be stored in a refrigerator. Shake well before taking. After 14 days amounts not used should be thrown away (flushed).
- If you have any questions about ampicillin, ask your doctor or pharmacist.

A Survey of Patients' Receipt of Prescription Drug Information

LOUIS A. MORRIS, Ph.D.

A nationwide telephone survey of 1,223 individuals investigated the nature and source of information provided to patients regarding prescription drugs. About half of the respondents said that they had received information from their doctor about the purpose and directions for use for their most recent prescription. Only a few people (11 per cent) said that they had been informed about the drug's side effects, and 19 per cent said that they had been told nothing by their doctor. Most (72 per cent) related that nothing had been said to them at the pharmacy. Written information (stickers on the medicine container, leaflets or brochures) was said to be infrequently provided at the pharmacy. About 12 per cent of the respondents said they had expected they might get a drug side effect, but only 9 per cent said that they had experienced one. The most frequently cited action in response to side effects was to consult the physician (40 per cent); however, a sizable percentage of people stopped the medicine completely or temporarily (36 per cent) or kept on taking the drug as prescribed (32 per cent).

THE MOST COMMON FORM of medical treatment rendered by physicians is the prescribing or administering of a drug. Two thirds of the ambulatory therapeutic services given in physicians' offices involve the use of prescription drugs.¹ According to a recent survey, about a quarter of the adult U.S. population took a prescription drug during the past 24 hours.²

Numerous scientific journals, academic and government publications, and drug

industry promotional materials provide a constant flow of information to prescribers and dispensers of these medicines. In this manner, professional decisions can be made on the basis of the best scientific information available. However, the flow of information to consumers about prescribed medicines is considerably more confined. By legal definition, a drug is marketed on a prescription basis, rather than made available over the counter, because of its potential to cause harm.³ To avoid dangerous interactions with foods or other drugs and to avoid hazardous activities, it may be argued that consumers need to know certain precautions about prescribed medicines. Also, prescription medicines often have side effects associated with their use. Providing consumers with information about side effects may allow better recognition, interpreta-

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tion and knowledge about preventive or remedial action.

In addition to precautionary and side-effect information, consumers also need proper instruction on how to use drugs so that medicines will produce their intended benefits. Several literature reviews suggest that 30 to 50 per cent of patients do not adhere to prescribed regimens,⁴⁻⁶ frequently missing doses, consuming too much or too little medicine, prematurely discontinuing the regimen or improperly spacing doses. Although there are many reasons for this large-scale failure to adhere to the regimen, a significant proportion of the problem can be traced to inadequate communication between physicians and patients.^{7,8}

For individuals using prescription medicines on an outpatient basis, the physician is often viewed as the primary expected source of information. Studies done in this country and abroad reveal a wide range of estimates of the amount and type of information provided to patients.⁷⁻¹³ Much of this variance may be attributable to the nature of the population under study (i.e., age, disease type, patient status, treatment facility, etc.) and the method utilized to collect data.

For example, Svarstadt,⁷ using direct observational techniques, found that physicians in a New York clinic informed patients about the length of therapy 10 per cent of the time and dosage frequency 17 per cent of the time. For 17 per cent of the patients, the drug was never discussed. In a telephone survey, Hoff⁹ found that 48 per cent of 415 respondents reported that they had not talked to their doctor when their most recent prescription was written. Boreham and Gibson interviewed 80 Australian female patients.¹⁰ During initial consultation, physicians provided information on a drug's name, purpose and effects, and gave instructions for treatment to about one fifth to one third of the patients. Information about side effects was provided to

15 per cent of the patients; however, this disclosure was most frequently spurred by patient questioning. During follow-up consultations, about half of the patients were apt to be informed about a drug's name, but other information was infrequently provided. Taken as a whole, these studies suggest far less than optimal communication of prescription drug information from physician to patient.

Another potential source of information for the patient is the pharmacist. Pharmacists are in a central position in the drug distribution system to inform patients about prescription drugs, and numerous studies have demonstrated clear benefits of pharmacist counseling. However, studies that have used direct observational methods reveal that only 0 to 20 per cent of patients filling prescriptions receive meaningful information about their prescription.¹⁴⁻¹⁶ A study of 95 midwestern pharmacies¹⁷ found that in 41 per cent of the pharmacies some oral or written information was provided when the drug was dispensed, but the quality of information was rated as poor. Campbell and Grisafie¹⁸ found that in Washington State, where regulations require pharmacists to counsel patients, about half of the pharmacists studied provided information on how to use a specific product, but only 8 per cent provided an important precaution about use of the drug. In addition to oral sources of information, there are a number of printed sources potentially available to the consumer.¹⁹ These sources range from small stickers to be affixed to the medication container to multipage brochures and pamphlets.

Previous studies provide a glimpse of the information environment surrounding consumers' use of prescription drugs. Due to regional differences, small samples and vast differences in data collection methods, the emerging picture (especially that part involving physician delivery of drug information) is sketchy.

The purpose of the present study was to provide a more complete overview of consumers' receipt of prescription drug information. How much and what type of information is being provided by health professionals? What other sources of information (friends, relatives, printed media) provide information to consumers? A second purpose was to provide data from a broad cross section of individuals regarding how information influences drug use experience, specifically the experience of drug side effects. What proportion of the people taking drugs experience a side effect? Is the side effect expected, and what is done in response to its occurrence?

To gather information in a cost-feasible manner, a national telephone survey was undertaken. This method enables the solicitation of a wide range of information from a broad cross section of the population. Several studies have found that telephone interviews yield generally comparable data to personal interview and mail surveys.²⁰⁻²² Many suspected forms of bias related to telephone interviews, such as restricted access to telephones by certain population segments and unwillingness to answer sensitive questions over the phone, have not been confirmed in systematic evaluations. However, other forms of response artifacts have been shown to influence responding. For example, the pacing of questions and the time allowed for recall of events may influence subject reporting. For example, Siemiatycki²⁰ found less underreporting of doctor visits when respondents answered questions via mail survey compared with telephone or personal interviews. Thus, in the present survey care was taken to fix an experience in the subject's mind (the last time a prescription was filled) in the beginning of the survey and to ask a series of questions related to that experience. This form of questioning has the advantage of soliciting information on reported experience, rather than global attitudes or opinions. How-

ever, its major disadvantage is that it relies solely on the subject's memory. Respondents may have forgotten, misperceived or incorrectly recalled events or details of events. Thus, results must be carefully interpreted as based on subject memory, and study conclusions must be couched as tentative, to be confirmed by observational studies.

Method

A national (continental U.S.) survey of telephone households was conducted in the summer of 1979. Selection of telephone numbers was accomplished via a three-stage sampling technique. At the first stage, each of the 30,000 telephone exchanges (the first three digits of the telephone number) currently in use was assigned to one of nine census tract sampling strata. Exchanges were then ranked by the size of the population covered and placed in sampling blocks of 55 exchanges. Two telephone exchanges were then chosen at random from each block.

In the second sampling stage, telephone households were identified via a computer-generated random four-digit suffix. Prior to issuing the selected telephone suffix, a computer program checked the selected number against information in storage regarding whether the selected number was a residential telephone number. The fourth and fifth digit of the telephone number are coded separately for businesses and residential phones. In this manner, approximately 70 per cent of the nonworking or business numbers were eliminated before the telephone number was identified for the interviewer.

The third stage of the process consisted of selecting the eligible survey respondent within the household. Individuals 18 years of age and older were considered eligible for the study. Interviewers obtained information from the individual answering the telephone on the number of adults (over

the age of 18) in each contacted house. By virtue of a precoded random schedule, one individual was selected for interviewing in each household.

To improve response rates, up to five calls, distributed on day, nights and weekends, were made to each selected number. People who were too busy to be interviewed were called a second time and asked to complete the interview. In addition, a nonresponse follow-up was conducted on a sample of numbers for which there was no answer, busy numbers and numbers for which the selected individual was not at home. The follow-up consisted of a second round of four telephone calls. The noncontacted telephone numbers were reviewed with the telephone company to classify them as working, nonworking or nonhousehold. Table 1 outlines the sample dispositions. Of 3,580 telephone numbers called, 1,610 households were identified. In all, 1,223 subjects completed the survey; 1,180 were questioned on the initial round of telephone calls, and 43 subjects were added by the nonresponse follow-up. This yields an overall response rate of 76 per cent.

Interviewers for the study had experience with previous telephone surveys. All were familiar with interviewing techniques, and all were briefed on the general purpose and on specific questions

for this study. Role-playing techniques were used to identify possible problems prior to the study, and interviewers were periodically monitored by interviewing supervisors throughout the data collection period.

Questionnaire Design

Those individuals consenting to be interviewed were told that the purpose of the study was for the Food and Drug Administration to find out more about their experiences with medicines. To place the respondent in an experiential rather than an attitudinal frame of reference, respondents were first asked to recall the last time they had a prescription filled for themselves. Interviewers then proceeded to ask a series of questions about the respondents' experiences filling the prescription; what respondents were told about the medicine(s) from their doctor, pharmacist and friends; and whether they received any written information. Data on experience using the drug and reasons for taking the drug were solicited, and a question about educational background was posed. A list of the questions posed is presented in the Appendix. Subjects who stated that they never had a prescription filled for themselves ($N = 48$) and those who did not remember ($N = 62$) were asked to talk about their experiences during the last year filling a prescription for another family member. Fifty-four respondents remembered filling a prescription for a family member. Since about half ($N = 21$) of these prescriptions were for a child, these data were considered along with those for respondents who remembered filling prescriptions for themselves.

Results

Subjects in the sample ranged in age from 18 to 92 years, with a mean age of 44. Fifty-eight per cent were female. About 78 per cent had graduated from high school,

TABLE 1. Sample Selection Dispositions

Telephone numbers called	3,580
Nonhousehold (business, nonworking)	1,572
No answer or busy	398
Identified households	1,610
Ill, indisposed	12
Language barrier	75
Refusals	236
Call backs (for identified respondents)	78
Original respondents	1,180
Those added by follow-up	43
Total respondents	1,223

and 41 per cent had at least some college education.

Subjects were asked a series of questions describing the circumstances when their most recent prescription was filled. Three fourths said that they had filled a prescription for a single medication at that time, and most others (15 per cent) said that at least some of the drugs had been taken on a previous occasion, with 41 per cent of these people refilling an existing prescription. Most of the respondents (83 per cent) said that they themselves had picked up the medicine at the pharmacy, and 62 per cent of the time the medicine was said to have been given to them by a pharmacist rather than by a clerk. Approximately 12 per cent said that they had filled their most recent prescription within the preceding week, 18 per cent one to four weeks previously, 30 per cent one to six months previously, 17 per cent six to twelve months previously and 25 per cent more than a year previously.

Overview of Information Provided

Subjects were asked to recall freely what, if anything, they had been told by the person who sold them the medicine(s). Up to four responses were recorded for each respondent. Table 2 lists the type of information provided. Seventy-two per cent of the people answering this question said that they had not been told anything about the medicine. The most frequently provided information concerned directions about how and when the medicines should be used. Side-effect information was infrequently provided. However, one in five people taking headache remedies or birth control pills said that they had been told about side effects at the pharmacy.

In addition to verbally supplied information, 8 per cent (73 respondents) said they had been given written material in addition to the label on the medicine container. About half (41 per cent) of the provided

TABLE 2. Oral Information Provided at Pharmacy

Information	Number	Per Cent*
Directions for use	196	21
Side effects	42	5
Purpose of medicine	44	5
General (expiration date, refills, price)	48	5
Nothing was said	673	72
Total	1,103	

* Sums to over 100%; 932 people answered this question, up to four responses were recorded for each.

information was said to be stickers for the medicine bottle, with the rest receiving brochures, pamphlets or instruction sheets. About half (55 per cent) of the 47 people reporting that they had received longer forms of written information said they were taking drugs for menopause or birth control, cases for which written information is required to be dispensed by federal regulation.

To ascertain physician-supplied information, patients were asked to relate what, if anything, their doctor told them about the drug(s) when it was prescribed or while they were taking it. Again, up to four re-

TABLE 3. Oral Information Supplied by Physician

Information	Number	Per Cent*
Purpose	561	51
Directions—drug use	516	47
Directions—call/contact physician	56	5
Side effects	123	11
General (refills, read pamphlet)	27	2
Nothing was said	207	19
Total	1,490	

* Sums to over 100%; 1,101 people answered this question, up to four responses were recorded for each.

sponses were recorded. Table 3 lists the results for this question.

Clearly, subjects related that they were told a great deal more by their physician than by the pharmacist. About half of the respondents said that they were given information about the purpose of the medicine, and about half said that they were given directions about how to use it. Directions for use included information on when to take doses and how long to continue on the medicine. Only 5 per cent of the 516 subjects who said they received directions for use information related that they were given any precautions about taking the medicine (e.g., take with milk, avoid alcohol, etc.). About one fifth of these subjects said that they were told nothing about the medicine, but a small percentage of them (11 per cent) volunteered that no information was necessary because they were experienced in using the drug.

About one in ten were told about side effects. In 12 per cent of these 123 cases, the information relayed was that there would be no side effects. Side-effect information was most frequently provided to people taking birth control pills (said to be relayed to 46 per cent of those taking this drug). The other drugs for which side-effect counseling was said to be provided to more than about one in five people were drugs used for dieting, menopause, headache and allergies.

Only about 5 per cent of the respondents related that they were told when to contact the physician again. Of those informed, the reason for the contact was fairly evenly divided among three alternatives: a prearranged date (32 per cent); if there were side effects (30 per cent); and if there was no improvement (30 per cent). Only 12 per cent said that they had been given general information, such as refill instructions. This general information category included respondents who said that their physician told them to read the pamphlet that comes with the medicine. This oc-

curred primarily for birth control pills and menopausal drugs; eight of 53 respondents taking these drugs said that their doctor had told them to read the patient package insert.

In addition to the physician and pharmacist, patients may receive information about the drugs they are taking from their friends and relatives. When asked if their friends and relatives told them anything about the medicine, the most frequent answer was "no" by 89 per cent of the respondents. However, 42 per cent of those taking birth control pills and 26 per cent of those taking menopausal drugs said that their relatives did talk to them about the medicine.

Experience of Side Effects

One treatment outcome that may alter the course of drug therapy is the patient's experience of drug side effects. Only 9 per cent of the respondents said that they experienced a side effect when they took their medicine. Twelve per cent of the respondents signified that they had expected a drug side effect before they took the medicine. Forty-six of the 108 people (43 per cent) who had side effects said they had expected one, whereas only 10 per cent of those who did not have a side effect said they had expected one. The expectation of side effects was greatest for those taking medicines for dieting, birth control, headache, allergies and menopause. The experience of side effects was most frequently reported by those taking drugs for dieting, allergies and headache.

When the people were asked how they knew they might get a side effect, the most frequently provided reasons were that they were so informed by their physician or that they had previous experience with the medicine. The only exception was for women taking birth control pills, two thirds of whom said they had read about side ef-

fects in a pamphlet. Other reasons, given less frequently, are listed in Table 4.

The respondents who said that they had experienced a side effect were asked what they did about the reaction. Table 5 lists the response to this question. The most frequent reaction was to call the physician, although sizable proportions of the respondents said that they either did nothing or stopped taking the medicine completely. The type of action taken in response to drug side effects differed according to the type of condition being treated. The most common response for those taking a drug to cure an infection was either to stop taking the medicine or to continue on the regimen without consulting their physician. Only one quarter of the 44 people experiencing a side effect called their physician. For those taking medicine for a chronic condition, half of the 30 people experiencing a side effect called their doctor.

Discussion

As mentioned previously, one must be especially cognizant of the role of respondent memory when interpreting the results of this survey. First, respondents may have simply forgotten the last time they filled a prescription. Since only 9 per cent said that they had never filled a prescription or did not know when they filled a prescription, the great majority of respondents recalled some experience, even if it was not their most recent one.

A second, but perhaps more critical, issue is that memory is imperfect. It is likely that subject remembrances are distorted in at least two ways: 1) "leveling," or simply forgetting events or details of events that did indeed occur and 2) "sharpening," magnifying or creating details of events that never occurred. It is impossible to know the extent to which "leveling" and "sharpening" occurred in the present survey. One might expect that tabulating results based on the recency of prescription filling may have helped highlight memory

TABLE 4. Reasons for Expecting Side Effects

Reason	Number	Per Cent*
Previous experience	41	33
Read about it (newspaper, magazine)	5	4
Read about it (brochure/pamphlet/book)	15	12
Information on bottle	6	5
Doctor	52	42
Pharmacist	8	7
Relative/friend	14	11
Other	6	5
Total	147	

* Sums to over 100%; 123 people answered this question, up to three responses were recorded for each.

problems. This was attempted, but unfortunately these data are confounded with other factors (such as purpose of the medicine and previous use of the drug) that appear better able to explain the data patterns. Studies have shown that even when interviewed a few minutes after leaving the physician's consulting room, patients fail to report a third to half of the pertinent information provided at the visit.^{23,24} One may presume that respondent memory has an important bearing on the data results,

TABLE 5. Response to Side Effects

Response	Number	Per Cent*
Stopped medicine completely	29	27
Stopped temporarily	10	9
Called doctor	43	40
Called pharmacist	1	1
Kept taking medicine	35	32
Reduced dose	5	5
Rested/relaxed	8	7
Other	2	2
Total	133	

* Sums to over 100%; 108 people answered this question, up to three responses were recorded for each.

regardless of the time lapse between prescription filling and interview. A basic caution that must be applied in interpreting study results is that this survey represents the perception and memory of events rather than direct measurement of events.

With this caution in mind, it is apparent that verbal communication by the physician is the primary method of informing patients about drugs. The drug's purpose and usage instruction are reported to be received by about half of the subjects. It is clear that patients see their doctor as the most important source of drug information.^{25, 26}

The pharmacy is often considered an ideal place to receive drug information. Most said that the pharmacist personally gave them the medicine, but the majority of the respondents related that they were told nothing about the drug. When advice was given at the pharmacy, it was primarily on how to use the drug. It should be noted that patients were asked to recall physician-provided information given at any time during the course of treatment, whereas pharmacy-provided information was solicited only for the time the prescription was filled. Since only one respondent reported seeking advice from a pharmacist when side effects occurred, it is evident that pharmacist-provided information is most apt to be provided at the time the drug is dispensed. Respondents did report a greater likelihood of being counseled at the pharmacy if they were receiving a prescription they had not taken before. However, these differences were not large, and overall the majority reported receiving no advice. The general picture that emerges is that people remember being told very little about their drugs, with the exception (for half the respondents) of drug purpose and how to take the medicine.

The expectation that one may get a side effect was most likely to be conveyed by the physician or by previous experience using the medicine. The only exception was birth control pills, where two thirds said that information was conveyed in a

pamphlet. Interestingly, birth control pills and menopausal drugs were among those drugs for which subjects most frequently reported to have received side-effect information from their doctors. These drugs were also reported as being most often discussed with friends and relatives. Birth control and menopausal drugs were chosen as candidates for patient package inserts (PPIs) because of their risks and the elective nature of their use. The precise role of the PPI in promoting or reducing the amount of discussion about their use cannot be determined from this survey.

Due to the undetermined role respondent memory may have played in influencing the obtained data, this survey's results should be interpreted in light of other studies that used alternate methodologies. The results appear consistent with literature previously reviewed. In addition, a recent survey of pharmacies in 20 U.S. cities found that 72 per cent of the people filling prescriptions for conjugated estrogens did not receive any meaningful verbal counseling from the pharmacist.²⁷ This is the same percentage as that found in the present survey. Because conjugated estrogens are drugs for which pharmacists may not be as likely to counsel patients as other drugs, this concordance of data must be carefully interpreted in light of the methodological limitation of the present survey. A useful purpose for this data is to provide a baseline for future telephone surveys so that trends in drug education and patient counseling may be discerned.

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Appendix

Questions Asked*

1. How long has it been since the *last time* you had a prescription filled for *yourself*?
2. At that time, when you last had a prescription filled for yourself, was it for only *one* medicine or was it for *more than one*?
3. How many different medicines did you get filled for yourself at that time?

* Skip patterns and interviewer instructions are not reported. A second version of the questionnaire was used for respondents filling prescriptions for others. Sex and age of respondents were recorded prior to asking these questions.

4. When you had this (these) prescription(s) filled, was it the *first* time you had ever taken this (these) medicine(s), or had you taken it (them) before?
5. Thinking of the medicine(s) that you had taken before, was (were) the prescription(s) just being refilled by the pharmacy at your request, or did you or the pharmacy have to contact the doctor before having it (them) refilled?
6. Did you pick up the prescription(s) at the pharmacy yourself?
7. Who actually gave you the medicine(s) . . . was it the pharmacist, a clerk, or someone else?
8. What, if anything, did the person who sold you the medicine(s) tell you about the medicine(s)? Did the person say anything else?
9. In addition to the label on the medicine container, were you given any other written information at the pharmacy?
10. What kind of written information was this? Was it . . .
 - Brochures or pamphlets
 - Instruction sheets
 - Stickers on the medicine with instruction, such as "May cause drowsiness, etc."
 - Or some other type of written information?
11. What, if anything, did your doctor tell you about the medicine(s) when it was (they were) prescribed for you or while you were taking it (them)? Were you told anything else?
12. Did any of your friends or relatives tell you anything about the medicine(s) that was (were) prescribed for you?
13. Did you have any side effects or reactions when you took the medicine(s)?
14. Did you expect that you might have a side effect or reaction *before* you took the medicine(s)?
15. How did you know that you might have a side effect or reaction?
16. What did you do about the reaction you were having to the medicine(s)?
17. Please tell me what condition the medicine(s) was (were) prescribed for.
18. (A question asking subjects to rank importance of three side effects was included—data are not reported.)
19. And, finally, just one question about yourself. Would you please tell me the last grade of school you completed?

Satisfaction With Ambulatory Care and Compliance in Older Patients

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Predictors of satisfaction with ambulatory care and compliance in 267 older and 581 younger patients were determined. Each patient rated a 45-item satisfaction-with-care-scale. Race, SES, marital status, distance from clinic, severity of illness (as measured by physician ratings, self-health assessment, number of medications, number of diagnoses, and number of clinic visits and hospitalizations in the prior year), and physician expectations of improvement were entered as predictors into stepwise multiple regression analyses for the elderly and the young. Predictors of better satisfaction in the young were less severe conditions, being nearer to the clinic and having fewer prior clinic visits over the year. In the elderly, having fewer visits to the clinic, more expectation of improvement by the physician and less severe conditions were associated with better satisfaction. Severity and clinic visits were predictors in each age group. The young, however, were also influenced by distance from the clinic. The elderly were influenced separately by the physician's prognosis. Thus, when the more impaired elderly are seen frequently without expecting a benefit, their satisfaction with care is poor. Further, satisfaction with care was correlated significantly with compliance in the elderly but not in the young. Findings suggest that improving satisfaction with care might also improve rates of compliance with the medical regimen in older patients.

SATISFACTION WITH MEDICAL CARE and compliance with a medical regimen are two variables often studied in health care. Generally, studies deal with one or the other variable alone; less frequently, they deal with the association between these two aspects of care. It has been pointed out that satisfaction with care has been viewed both as a determinant and a consequence of utilization.¹ Cafferate,² however, noted

that the two views are not incompatible, and that feedback and reciprocal relationships may be present. Satisfaction with care has often been included among patient outcomes regarding quality of care,^{3,4} and this would appear justified. Compliance has sometimes also been seen as an outcome of care, although it might better be classified as an intermediate variable influencing outcome as measured by disability, death or disease, since compliance and noncompliance may result in differential outcomes along these lines.⁵ In some instances, it seems logical that satisfaction with care received would be predictive of whether or not patients complied with the regimens prescribed. In this respect, satisfaction would be an independent, and compliance a dependent, variable.

Some determinants of satisfaction with care have been reported. A trend toward

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greater satisfaction with care in older persons was found by Gerst,⁶ particularly among older males; however, Hulka et al.⁷ identified lower satisfaction among patients over the age of 60, particularly in older blacks. Others⁸ have reported no relationship between satisfaction with care and demographic variables. Greater severity in regard to illness and disability has been found to accompany lower satisfaction with care,^{9,10} and in at least one study,¹¹ satisfaction was associated with compliance.

Becker et al.¹² concluded that patient noncompliance has become the best documented but least understood health-related variable. Most studies^{13,14} have found that approximately a third of their patients failed to follow physicians' recommendations. Adherence to instruction has been reported to be extremely low in low-income patients, for whom noncompliance reached 60 per cent or higher.¹⁵ Age extremes have been found to relate to noncompliance, with the very young resisting bad-tasting medicines and the very old simply forgetting to take their medications.¹⁶ Kasl and Cobb¹⁷ believed that compliance studies had focused too much on demographic variables rather than on attitudes and perceptions in explaining whether or not patients were compliant.

In previous studies, satisfaction with care was found to be associated positively with older age among ambulatory care patients¹⁸ and among patients treated for burns in emergency rooms.¹⁹ In regard to compliance, no differences were found between the young and the elderly in the way they adhered to medical regimens.²⁰

This study was an attempt to determine, first, if satisfaction with care differed in a group of young and elderly outpatients and, if so, which demographic and health variables significantly predicted levels of satisfaction for each age group. Finally, the relationship between satisfaction with care and compliance was determined for each age group. The hypotheses were that

higher satisfaction with care would be found in older patients, that different predictors would be associated with satisfaction for the elderly as compared with the young, and that satisfaction in both age groups would be positively associated with compliance.

Method

A sample of 878 male patients attending ambulatory clinics in a Veterans Administration (VA) medical center were randomly selected during a three-year period. Patients were entered in the study if they had been known to the clinic for at least 12 months, and signed informed consent for interviews at baseline and two months later. Only 12 patients did not agree to participate. Information on age, race, social class (Hollingshead's two-factor index²¹), marital status, education and self-assessed health, measured on a 6-point scale ranging from very good to very poor, were obtained from the patients. Patients also completed the 45-item Satisfaction with Physicians and Primary Care Scale of Hulka et al.²² Items are grouped into areas by content that measure satisfaction with the professional competence of physicians, personal qualities of physicians and cost/convenience of care. Although items can be grouped into these areas, most studies have reported the total score as a single measure of degree of satisfaction with care. Items are rated on 5-point scales, from strongly agree to strongly disagree, with some of the items phrased negatively and some positively. Higher scores represent a more negative attitude about care.

Twelve physicians provided care to the patients. They estimated severity of patients' conditions on a 6-point scale corresponding to that used by the patients for self-assessment. They also provided ratings on expectation in regard to patients' conditions two months later on a 3-point scale of better to worse.

Patients were followed up two months after they entered the study, and com-

pliance with the medical regimen and other variables were assessed. In regard to measurement of compliance, all medications prescribed were documented from physician orders in the medical records and hospital pharmacy reports. Kind, amount and duration of prescriptions at the time of the index visit and for the subsequent two months were recorded. Non-medication treatments, such as diets, special therapy or return visits to the clinic, were included for evaluation. At the home visit, the research nurse asked patients to recount what the physician had told them in regard to instructions for care. This was checked with data obtained from the records. Patients were asked if they adhered all, part or none of the time to each. They were then asked to show the nurse the bottles and containers of medications, and either a pill count or estimate of the amount of liquid in the bottle was made for comparison with the pharmacy record of what had been given to the patients. The information from the home visit, along with that from hospital records, was given to two physicians, who independently rated the degree of compliance on a 3-point scale, ranging from very compliant to very non-compliant. Physicians were blind to the age of the patients and other variables under study.

Also at the time of the home visit, patients were asked if they perceived their health to be better, the same or worse (3-point scale) than it had been two months previously. Patients also estimated their health status on a 6-point scale. Number of visits to the clinic or to non-VA physicians, or medications not prescribed by the VA were recorded for the two-month interval between baseline and follow-up visit.

Medical records of all patients were reviewed to determine the current number of diagnoses and medications, as well as number of clinic visits and hospitalization during the year preceding the date of intake into the study.

Data were analyzed by first comparing the level of satisfaction with care between

patients aged 65 years and older ($N = 267$) and those under the age of 65 ($N = 581$) with a *t*-test between means. Satisfaction with care was then predicted separately for each age group by entering 12 variables collected at baseline into a stepwise multiple regression. Predictors were personal characteristics (race, education, social class and current marital status); distance from clinic; severity of illness (self-assessed health, number of diagnoses, number of medications, severity assessed by physicians and expectation of improvement as judged by the physicians); and utilization of care during the prior year (number of clinic visits and hospitalizations). The final step was to correlate level of satisfaction (baseline) with degree of compliance (two months later) for each age group separately.

Results

Satisfaction in the younger group was 119.6 ($SD = 13.2$), and that in the older group was 113.8 ($SD = 12.4$). Range for the scale was 45–225, with a lower score reflecting more satisfaction with care. Since these represent approximately midpoint values on a 5-point scale, it might be assumed that both groups were relatively satisfied with their overall care. In examining the particular areas of satisfaction, each group rated professional competence of physicians about the same (young = 37.20, elderly = 36.37), but the younger group was more negative than the older group on items related to personal qualities of physicians (37.42 v. 35.56) and cost/convenience of care (46.04 v. 41.82).

Table 1 shows the values for the items that were entered into the regression analyses predicting satisfaction with care. The average age of each group is also shown. In the younger group, the average age was 49 years, with a range of 23 to 65. The age of the older group averaged 69 years, with a range of 65 to 98. Approximately 13 per cent were black, which corresponds to the average in the state of

TABLE 1. Means and Percentages of the Variables Used to Predict Satisfaction With Care in Older and Younger Patients

Variables	Young (N = 581)		Older (N = 267)	
	Mean	Per Cent	Mean	Per Cent
Personal characteristics				
Age	49.1		69.3	
Black		11		05
Education (years)	12.1		10.8	
Social class	3.3		3.5	
Current marital status		80		75
Distance from hospital (miles)	21.4		19.4	
Severity of condition				
Self-assessed health	3.0		2.8	
Number of diagnoses	3.2		3.8	
Number of medications	3.6		4.0	
Severity (by MD)	3.7		3.8	
Expectation of improvement (by MD)	1.6		1.8	
Utilization				
Number of clinic visits prior year	4.8		5.4	
Number of hospitalizations	1.7		1.7	

Note: Self-assessed health rated 1-6, with higher worse; severity rated 1-6, with higher worse; and expectation of improvement rated as 1 = better to 3 = worse.

Florida. Most were middle class, and approximately three fourths were married. Patients lived about 20 miles from the clinic, perceived their health as fair to good, averaged approximately three diagnoses and three to four medications, and

were estimated by the physicians to be more severely ill than they viewed themselves. On the whole, physicians expected these patients to be about the same or slightly worse in two months.

All but 30 patients were followed up at two months. This represented a 3 per cent loss of follow-up data. Twenty-one patients (4 per cent) were in the younger, and nine (3 per cent) were in the older groups. The 30 patients lost to follow-up did not differ significantly on any of the demographic or satisfaction variables collected at baseline when they were compared statistically. Table 2 shows the follow-up data. It can be seen that a very small number of persons had been seen by the clinic during the two-month interval. Ambulatory care clinics generally schedule patients every three months for follow-up, unless otherwise indicated. This was one of the reasons a two-month follow-up time had been selected. No patients had been admitted to the hospital during the follow-up period. Medications were essentially the same as those that had been prescribed at baseline. No non-VA physicians had been consulted

TABLE 2. Means of the Variables Collected at the Two-Month Follow-Up for Older and Younger Groups

Variables	Younger (N = 581)	Older (N = 267)
Number of additional visits	.02	.03
Number of hospital admissions	.00	.00
Number of medications	3.61	4.03
Patient evaluation of improvement	1.71	1.59
Self-assessed health	3.10	2.76
Compliance (by patient)	1.40	1.37
Compliance	1.52	1.48

Note: Patient evaluation of improvement was rated 1-3, from better to worse; self-assessed health was rated 1-6, with higher worse; and compliance was rated 1-3, with 1 being compliant all of the time, 2 part of the time, and 3 being mostly noncompliant.

by the patients during the follow-up period. The patients' evaluation of their condition on a scale of 1-3, with 3 being the worst, was 1.7 for the young and 1.6 for the old. The correlation between the physician's expectation of patients' conditions two months later and the patients' ratings at that time was $r = 0.29$ for the young and $r = 0.08$ for the elderly. The correlation between patients' self-assessed health at baseline and two months later was relatively high ($r = 0.48$ for the young and $r = 0.59$ for the elderly). The correlation between self-assessed health and the physician's severity rating on the same scale at baseline was $r = 0.48$ for the young and $r = 0.26$ for the elderly. The mean score on compliance, using the patients' estimate, was 1.4 for the young and 1.4 for the elderly, with 1 being compliant all of the time and 3 none or almost none of the time. Average ratings of 1.52 and 1.48 were given by the physicians judging compliance for the two age groups. The agreement between the two physicians was $r = 0.72$. The difference between the elderly and

the young was not statistically significant ($t = 0.34$).

Predicting Satisfaction with Care

Tables 3 and 4 show that three of the 12 variables significantly predicted satisfaction with care in each of the age groups.

As seen in Table 3, the best predictor of satisfaction in younger patients was severity of condition, as rated by the physician. Those who were more severely impaired were less satisfied with care. The next best predictor, in combination with severity, was miles from the hospital, which added to knowing severity at a 0.01 level of significance. The longer the distance from the clinic, the more was the dissatisfaction with care. The only other variable to add significantly to predicting satisfaction with care was number of clinic visits ($p < 0.05$), with more visits also associated with less satisfaction. These three variables accounted for 70 per cent of the predictable variance. All 12 predictors together accounted for 23 per cent of the total variance in satisfaction with care. Although several

TABLE 3. Predictors of Satisfaction With Care in 581 Patients Under the Age of 65

Predictor Items	r	Cumulative R^2	ΔR^2	Per Cent Predicted R^2
Severity rated by MD	0.34*	0.11	0.11	48
Distance from clinic	0.21*	0.14	0.03	61
Number of clinic visits	0.18*	0.16	0.02†	70
Current marital status	0.08†			
Education (years)	0.06			
Self-assessed health	0.13*			
Number of diagnoses	0.03			
Social class	0.14*			
Number of medications	0.04			
Black	0.09†			
Expectation of MD	0.04			
Number of hospitalizations	0.13*		0.07	
Using All Predictors		0.23		100

* $p < 0.01$.

† $p < 0.05$.

Note: Higher scores on satisfaction are worse, severity rated 1-6, with higher worse; self-assessed health 1-6, with higher worse; social class 1-5, higher = lower class; and expectation of physician 1-3, with higher worse.

of the other variables were significant at a zero-order level in their association with satisfaction, they did not add uniquely at a significant level to the cumulative variance.

Table 4 indicates that two of the same variables were also among the best predictors in the older group. Number of clinic visits was the best predictor and severity of illness, as judged by the physician, the third best predictor ($p < 0.05$). The second best predictor, however, was different from those identified in the young. The expectation of the physician as to whether the patient would improve or not in the next two months added significantly to number of clinic visits at a 0.01 level. Those patients whom the physician expected to be better were more satisfied with care. The interesting point is that even though there was probably overlap between physician expectation, number of clinic visits and severity, each measure something unique in itself in that each adds significantly to the other. Again, as with the younger group, there were other variables as-

sociated significantly with satisfaction at the zero-order level. They were, however, redundant variables and in combination with the three predictors did not add significantly to prediction. Among this older group, 77 per cent of the predictable variance was accounted for by three predictors. All 12 variables accounted for 22 per cent of the total variance in satisfaction with care among the elderly.

Correlation of Satisfaction with Compliance

The association between level of satisfaction at baseline and compliance two months later was $r = 0.41$ in the older group (significant at $p < 0.01$) and $r = 0.04$ in the younger group, which was not statistically significant. Table 5 shows how each of the areas of the scale related to compliance. None was associated with compliance in the young, and all were related to compliance in the elderly. In particular, the personal qualities of the physician and cost/convenience of care were more

TABLE 4. Predictors of Satisfaction With Care in 267 Patients Over the Age of 65

Predictor Items	r	Cumulative R ²	ΔR^2	Per Cent Predicted R ²
Number of clinic visits	0.32*	0.10	0.10*	45
Expectation of MD	0.28*	0.15	0.05*	68
Severity by MD	0.16*	0.17	0.02†	77
Distance from hospital	0.11†			
Number of medications	0.13†			
Current marital status	-0.13†			
Number of diagnoses	0.18*			
Race	-0.08			
Social class	0.05			
Education	0.03			
Self-assessed health	0.07			
Number of hospitalizations	0.12†		0.05	
Using All Predictors		0.22		100

* $p < 0.01$.

† $p < 0.05$.

Note: Higher scores on satisfaction are worse, severity rated 1-6, with higher worse; self-assessed health 1-6, with higher worse; social class 1-5, higher = lower class; and expectation of physician 1-3, with higher worse.

closely related to compliance in the older group than was the professional competence of the physician.

Discussion

The hypothesis that the older patients would be more satisfied with care was supported. The finding that the younger patients were more dissatisfied in regard to items that measured the convenience of care is somewhat understandable. Many in this group were employed and may have had long waits when they came for appointments. They also lived an average of a few miles farther away from the clinic than did the older group. Elderly patients are perhaps less likely to complain about long waits and sometimes even see the clinic visits as a social event. Furthermore, the elderly as a group may be less likely to report problems. For example, they are known to overestimate favorable health in comparison with objective health measures,²³ and the same could be true for their satisfaction-with-care ratings.

The hypothesis that there would be different predictors for satisfaction in the two age groups was only partially supported. Two variables, clinic visits and severity, as judged by the physician, were predictors for both age groups (although differing in order of importance). The greater the severity estimates by the physician, the more dissatisfaction was found in each age group. However, severity accounted for most of the variance in satisfaction in the young but was the third best predictor in the old. Severity of condition has been found to be associated with satisfaction in other studies,^{6,8} in a similar way. The fact that it was more associated with satisfaction in the young than in the elderly in this study may indicate that when age is taken into account, older patients are more likely to accept some chronic conditions as a natural part of aging. Number of clinic visits was the best predictor of satisfaction in the elderly, with more visits associated with less satisfaction. This same variable de-

TABLE 5. Correlations Between Satisfaction With Care and Later Compliance for Two Age Groups

Satisfaction Variables	Correlations With Compliance	
	Young	Elderly
Professional competence of MDs	0.02	0.07*
Personal qualities of MDs	0.01	0.22†
Cost/convenience of care	0.05	0.44†
Overall satisfaction	0.04	0.41†

* $p < 0.05$.

† $p < 0.01$.

Note: Higher scores on satisfaction are less satisfied, and higher scores on compliance are less compliant.

scribing clinic visits was the third best predictor in the young. While it can be concluded that clinic visits and severity add to each other in prediction, indicating that each measures something unique, it is also likely that there is considerable overlap between the two in regard to both being measures of severity as viewed by the physician who schedules appointments.

The predictors that differed between groups were distance from the clinic in the young and physician expectations of improvement in the old. As mentioned, distance may be particularly important to the younger patients if they must take time off from work, and it is likely to influence their ratings of satisfaction when convenience with care is evaluated. The expectation of the physician regarding prognosis helped to explain satisfaction with care in the elderly. This can perhaps be explained by looking at the combination of predictors in each group. In the young, it was more severity, longer distance from the hospital and more clinic visits that were associated with dissatisfaction. In the elderly, it was more frequent visits, less expectation for improvement and more severity that predicted dissatisfaction. One could argue that this combination in the elderly, all influenced by the physician, represented

"more severity" as viewed by the physician. At the same time, however, the correlation between how the physicians viewed the patients in regard to severity and how the patients viewed themselves was not as highly correlated in the elderly as in the young. Thus, the older patients rated their health as better than did the physicians. One might ask which was the more valid assessment. Generally, it is assumed that the physician's assessment is the objective measure. Therefore, in most studies^{18,23} the elderly have been found to overestimate their health as favorable in comparison with physician estimates. Conversely, how much the physician's estimate is influenced by his/her views on aging, particularly in regard to some stereotype of the elderly as frail and weak, is not known. The issue here is not so much which view was right, but rather that patient and physician views were incongruent for some of the elderly.

It seems obvious that the patient and physician need to share some common understanding about the person's condition and treatment. With the elderly, however, this may represent a dilemma. It has been shown in other studies^{23,24} that older peoples' assessment of their health was highly related to their functional status. Some persons with poor objective health ratings perceived their health as good and continued to function adequately in everyday activities of living, while others who saw their health as poor, without any objective evidence of this severity, did poorly in physical functioning. The relevant question would appear to be that of how physicians and patients can get together on their views, so that treatment starts from a common base. This takes on added significance in light of other studies, in which lack of congruence between physician and patient, as well as severity of the patient's condition, were found to be associated with compliance with the medical regimen. The health belief model described by Rosenstock²⁵ and elaborated

upon by Becker¹² suggests that patients must perceive their condition as serious and treatment to be of potential help in order for compliance to be assured. However, the health belief model deals more with preventive health care than with chronic, ongoing health problems, although some would suggest that the same model applies for both kinds of care.

If the patient is made to see his/her health as poor, whether this information is transmitted directly or indirectly by the physician, compliance might be increased, but possibly at the expense of a self-fulfilling prophecy. The older person would have to change his/her self-image from that of someone in good to someone in poor health, and as a result might function less well (unless the treatments prescribed were indeed a powerful remedy).

On the other hand, physicians cannot be expected to change their views about the severity of the condition, if they have made their prognosis on the basis of individualizing the patient and not on a stereotype of the elderly as a group. Most of the elderly under care have multiple chronic conditions. Furthermore, they live with these conditions for a considerable time. Cure is not usually the objective for these patients, as compared with younger patients with more acute illnesses. It is expected that physicians would become frustrated that treatments are not always available to improve the patients' conditions significantly. With the elderly, having someone who understands their condition, someone on whom they can rely, and someone to whom they can turn when they perceive their health worsening, is very important. This requires frequent visits of short duration, during which the "caring" role of the physician is uppermost. Medications are sometimes then adjuncts to maintaining functional status.

Finally, the differential effect of satisfaction on compliance by age was somewhat unanticipated. It had been hypothesized that satisfaction would be related to com-

pliance significantly in both age groups, but only in the older group was a significant association between the two found. Age groups did not differ in regard to level of compliance, with noncompliance being present in each age group. It should be recognized that the level of association between satisfaction and compliance that was found in the elderly could only be considered moderate. In other words, other factors, not measured by satisfaction with care, still predict a large proportion of the variance in compliance. However, in the younger group no relationship between the two existed, at least in terms of the variables used in the study to measure satisfaction. It is tempting to speculate that since the physician's expectation influenced satisfaction in the elderly, when the physician did not believe that his/her contact with the patient was helpful, somehow the patient sensed this in the physician's attitude and thus put little faith in the medical regimen as well.

In summary, this study highlights some of the variables that impact on satisfaction with medical care in young and elderly, and suggests that in the elderly, satisfaction influenced compliance with the medical regimen. Findings also suggest that for older patients there may be value in the physician's assuming more of a "caring" then "curing" role in expectation and prognosis. This, in turn, might lead to a reduction in rates of noncompliance for elderly chronically ill patients.

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Participants in Noncompliance Research: Compliant or Noncompliant?

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Patients have the option to participate in many investigations of non-compliance for medical recommendations. The question can therefore be raised about whether a tendency to volunteer for medical research is consistent with a tendency to comply with other medical treatment requests. In short, are volunteers or participants generally compliant relative to nonparticipants? This study examined past compliance for recommended follow-up appointments in patients who were requested to participate in a blood pressure assessment program and in a subsequent study on compliance for hypertensive regimens. Hospital records of the patients were reviewed for the two-year period that preceded the request to participate. Analysis of variance demonstrated significant differences in past compliance for participants and nonparticipants. In general, participants were compliant compared with nonparticipants. The results of this study suggest that investigations of noncompliance have used samples that are select for compliant behavior. The implications of this study on compliance research are discussed.

SEVERAL REVIEWS of the literature have criticized sample selection methods in research on compliance with medical regimens.^{1,2} However, investigations to support or refute those criticisms have not been conducted. This article first defines one area of sampling bias in compliance research and then reports an empirical investigation of the problem.

The general concern over sampling methods has been the degree to which the sample is representative of the population. Researchers usually obtain samples from clinical settings that are easily accessible, such as hospital outpatient departments or private medical practices. Patients in these settings may have characteristics that dis-

tinguish them from patients who are in other clinical settings and from patients who, although symptomatic, have not sought health care at all. Furthermore, patients who drop out of treatment before the sample is selected are likely to have characteristics that distinguish them from other patients.

In addition, since volunteers and non-volunteers are known to have different characteristics,³ the extent to which the sample represents the population is further compromised when patients have the option to participate in studies on compliance. One can only guess at the effects on measures of compliance when volunteer samples are used. One possibility is that patients who volunteer may do so because they are committed to the treatment under investigation and may be more likely to comply with the treatment recommendations. A second possibility is that patients who agree to participate in a study do so because of a tendency to be com-

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pliant, a tendency that may carry over to requests related to the treatment. If the sample consists of compliant individuals, investigation of noncompliance may be problematic.

Few studies on noncompliance for medical recommendations have directly addressed questions related to sample selection biases. Typically, comparisons are made among participants and non-participants on sociodemographic or psychological factors rather than on adherence to the regimen.⁴⁻⁶ However, one study has investigated differential compliance rates for participants and non-participants. In that investigation, psychiatric outpatients were contacted and asked to participate in a study done at a regularly scheduled appointment and taking several hours.⁷ The outcome measure of volunteer status was compared with psychological and sociodemographic data obtained at earlier appointments. Patient hospital records, obtained some time after the study, were also examined. It was found that 57 per cent of those who had volunteered had continued therapy or been referred elsewhere. On the other hand, 69 per cent of nonvolunteers had terminated early from the program.

The study is important since it suggests that nonparticipants in a study within a psychiatric setting also tend to be non-compliant. However, another interpretation of the data is possible. Negative experiences in the psychiatric clinic prior to the request may have precipitated both the refusal to participate in the psychotherapy study and the decision to drop out of therapy. Therefore, the compliance of the patient may not have been a factor in early withdrawal.

The literature, then, does not contain evidence to support or refute a view that participants in medical investigations are compliant. The purpose of the present study is to fill that void. It was hypothesized that compliance with medical recommendations made prior to a request to

participate in a clinical study would be lower for nonparticipants than for participants.

Method

Sample

Patients investigated in the present study had attended the Health Sciences Centre, Winnipeg, Canada, a tertiary care hospital located in the inner city. The hospital serves the entire province, but the ambulatory care departments (Primary Health Care, Outpatient Department and the Emergency Department) are used primarily by the population from nearby areas. Patients attending the ambulatory care departments are often from a lower socioeconomic level. In addition, the ambulatory departments are frequently utilized as a source of medical care by North American Indians (natives), who constitute a major ethnic group in the area.

A blood pressure screening program was conducted in the ambulatory care departments during the period of March 1978 to April 1979. Patients with recorded diastolic blood pressures of 100 mmHg or greater were invited to have further blood pressure assessment and were informed of the research nature of the program. After assessment, if the patients were found to require treatment, they were invited to receive care in a hypertension clinic in which compliance was to be investigated.

Five groups of participants and non-participants were identified on the basis of three criteria: responses to two requests to participate and hypertension status as determined by resting blood pressures taken during assessment (Table 1). The five groups were classified as follows.

1. Unknown-nonparticipant: patients who would not participate in blood pressure assessments and whose health status and need for treatment were therefore unknown.

2. Hypertensive-nonparticipant: patients who participated in blood pressure assessment and were found to require

TABLE 1. Criteria for Participant and Nonparticipant Groups

Group	Elevated Screening Blood Pressure	Response to Request to Be Assessed	Resting Blood Pressure Elevated	Response to Request to Participate in Compliance Study	Attended Compliance Study	N
Unknown-nonparticipant	yes	no	?	—	—	40
Normotensive-participant	yes	yes	no	—	—	40
Hypertensive-participant	yes	yes	yes	yes	yes	40
Hypertensive-nonattender	yes	yes	yes	yes	no	13
Hypertensive-nonparticipant						
Completed screening	yes	yes	yes	no	—	9
Did not complete screening	yes	yes	yes	no	—	25

treatment for hypertension, but refused follow-up.

3. Normotensive-participant: patients who agreed to participate in blood pressure assessment, but were found to be normotensive and therefore did not require follow-up.

4. Hypertensive-participant: patients who participated in blood pressure assessment, were found to require treatment for hypertension, agreed to participate in follow-up and did attend.

5. Hypertensive-nonattender: patients who participated in blood pressure assessment, were found to require treatment and agreed to participate in a follow-up program, but then did not attend.

There were 741 suitable patients identified through the screening program and distributed over the five groups as follows: unknown-nonparticipant (N = 259), hypertensive-nonparticipant (N = 80), normotensive-participant (N = 268), hypertensive-participant (N = 115) and hypertensive-nonattender (N = 19). The sample, in this study, was randomly drawn from these 741 patients.

Procedure

Lack of consistency in compliant behavior across treatment recommendations^{8,9} determines that comparisons among patients should be made on the same compliance measure. The measure

likely to be available for the largest number of patients was attendance, and it, therefore, was chosen for this study.

In this study, attendance was investigated for the time prior to the assessment request in order to control for the possibility that the request influenced later attendance for recommended appointments. The assessment program was separate from the ambulatory care departments, thus reducing the chance that prior experiences in the departments would influence decision to participate in assessment.

Two years of visits to the ambulatory care departments were reviewed for each patient. Since not all patients in the five groups had previously been requested to make return hospital appointments, information on the critical measure was missing in some cases. A minimum of three instances of physician-recommended return visits were necessary to admit a patient to the study. Thus, an ineligible patient would be one having fewer than three physician recommendations for follow-up in the two years prior to blood pressure assessment. The charts were randomly ordered and sequentially reviewed by groups until 40 cases per group were found. The exception was the hypertensive-nonattender group, with only 19 members, all of whom were included.

Each medical visit noted in the chart in the two-year period was reviewed for: compliance with each follow-up recommendation; address and employment status (recorded at the visit that precipitated referral to the assessment program); date of birth; gender; and ethnic group (native or non-native). This information was obtained for all patients, whether or not they met the criterion of three follow-up visits. Data on patients not meeting the attendance criterion (ineligible patients) were later analyzed to determine selection factors within this study.

For the purpose of this study, recommendations for follow-up visits consisted only of recommendations for visits by and with medical practitioners, since a restriction of this type ensured uniformity in the study. Therefore, visits for laboratory or clinical investigations and visits with nurses, dieticians, dentists and physiotherapists were excluded.

Some of the data that were collected require explanation. Attendance compliance was expressed as a ratio: total appointments kept to total appointments recommended over the two-year review period. Address provided the only consistent indication of socioeconomic status found in the chart, and this was coded using specific geographic borders defining: 1) the core area of the city; 2) regions adjacent to the core area; and 3) all other regions.

Employment status, routinely noted on admission records of nonscheduled ambulatory care visits, was obtained from the record for the date of the assessment contact. Ethnic status was not always noted by those making entries in health records, but patients who were North American Indian were often labelled. Therefore, the records of the patients were searched for any reference to ethnic status. If none was found, the patient was categorized as non-native.

Results

Cases Reviewed

In total, 393 patient charts were reviewed. The required 40 patients per

group who met the three-visit criterion were selected in the following groups: unknown-nonparticipant, normotensive-participant and hypertensive-participant. All patient charts for hypertensive-nonparticipants and hypertensive-nonattenders were reviewed, but only 34 and 13, respectively, met the selection criteria and were included in the study.

In the course of the review, it was noted that the hypertensive-nonparticipants could be subdivided into two groups. One group of patients preferred to return to private physicians for treatment of their hypertension (completers, $N = 9$). The other group consisted of patients who had failed to complete assessment or had declined treatment of hypertension without mentioning that they would consult a private physician (noncompleters, $N = 25$).

Some descriptive statistics suggested that there might be substantial differences between the two subgroups of the hypertensive-nonparticipants. Rates of alcoholism, blood pressure and age were not alike (Table 2). Therefore, it was decided to subdivide the group.

Since early analysis had given evidence of noncomparability of the two subgroups of hypertensive-nonparticipants, it became apparent that all data analysis for hypothesis testing would have to be accomplished with six groups of markedly unequal sizes. Both parametric and non-parametric analyses were employed (Analysis of Variance, Chi-Square and Irwin-Fisher test).

Ineligible Patients

Among the 393 charts reviewed, 226 did not meet the criterion of three recommended follow-up visits and were ineligible for the study. However, demographic and health-related data were obtained on the ineligibles to determine the nature of selection bias in this investigation.

Since a criterion of three recommended follow-up visits was employed, the ineligible patients differed from those investi-

TABLE 2. Characteristics of Hypertensive-Nonparticipant Completers and Noncompleters

Characteristic	Hypertensive-Nonparticipants	
	Completers	Noncompleters
Rate of alcoholism	11%	32%
Age		
Mean	52.7 years	41.8 years
Standard deviation	8.9	14.2
Screening diastolic blood pressure		
Mean	104.4 mmHg	107.6 mmHg
Standard deviation	5.1	6.9

gated in terms of total ambulatory visits and total recommended follow-up visits. Ninety-six per cent of ineligible patients had six or fewer ambulatory visits (28 per cent of eligible patients had as few visits). Of the 226 who were ineligible, 138 had no recommended follow-up visits, 67 had one recommended visit, and 21 had two recommended visits. The charts of these patients contained inadequate information on attendance compliance.

Besides medical visits, there were many other ways in which the eligible and ineligible patients differed. The patients from the two eligibility classes were compared on blood pressure, past history of hypertension, social problems, employment, ethnic group, gender and place of residence (Table 3).

Place of residence was significantly different for the two classes. Eligible patients lived in the core area more frequently than expected, whereas ineligible patients more frequently resided in areas beyond the core area. Patients admitted to the study probably were of a lower socioeconomic status than patients not admitted.

During the chart review, various psychosocial and environmental problems were noted in physicians' records. It was acknowledged that there are deficiencies in using recorded social problems because not all problems are noted by physicians, and those that are recorded may represent errors in documentation or biases of the

physician. However, the decision was made to use the information that was recorded while keeping in mind the potential bias when interpreting the data. Patients in the two eligibility classes were compared for the following categories of social problems: no problems noted, alcoholism and other problems. The category "other problems" was a combination of a number of low-frequency categories (involvement with the law, family and financial problems). Ineligible patients were less likely to have social problems noted in their charts than had been expected. The opposite was true for eligible patients.

The Irwin-Fisher test was used to compare the two eligibility classes on employment status. Ineligible patients were more likely to be employed. However, patients who were admitted to the study demonstrated no difference between employment and unemployment rates. As for ethnic group, ineligible patients were more likely to be non-native. Gender also was significantly different, with more males among ineligible patients.

No difference was found between eligible and ineligible patients for probability of blood pressure falling above or below the grand median of 102 mmHg. However, there was a significant difference in rates of documentation of past history of hypertension. Ineligible patients were less likely to have a past history of hypertension noted in their hospital records.

TABLE 3. Characteristics of Eligible and Ineligible Patients in the Study

Characteristic	Ineligible (N = 226)	Eligible (N = 167)	Statistic
Gender			
Male	144 (64%)	89 (53%)	Z = 6.58
Female	82 (36%)	78 (47%)	p < 0.05
Residence			
Core	70 (31%)	83 (50%)	$\chi^2 = 27.08$
Fringe	63 (28%)	55 (33%)	df = 2
Other	93 (41%)	29 (17%)	p < 0.005
Social problems			
None noted	153 (68%)	66 (40%)	$\chi^2 = 31.40$
Alcoholism	50 (22%)	64 (38%)	df = 2
Other	23 (10%)	37 (22%)	p < 0.005
Ethnic group			
Native	23 (10%)	70 (42%)	Z = 7.27
Non-native	203 (90%)	97 (58%)	p < 0.05
Employment rate	143 (63%)	72 (43%)	Z = 3.96
			p < 0.05
Past history of hypertension	32 (14%)	55 (33%)	Z = 4.41
			p < 0.05

Chi-square analyses done separately on eligible and ineligible patients, for participant and nonparticipant groups by ethnic status, place of residence, employment status and social problems, demonstrated no significant participant group differences. In addition, there were no participant-nonparticipant group differences for ineligible patients on documented past history of hypertension. This was not so, however, for some groups of patients admitted to the study: normotensive-participants had lower frequencies of previously documented hypertension, and hypertensive-participants had higher frequencies than expected.

Attendance

The attendance compliance ratio was determined by dividing the total attended recommended follow-up visits over the two-year review period by total recommendations for follow-up. Total recommended visits ranged from three to 69 (mean 7.7 visits, standard deviation 7.5). There were no significant group differences in frequency of medically recom-

mended visits or total ambulatory visits (recommended visits and visits initiated by the patient). Further, the simple correlations of the attendance compliance ratio with either total ambulatory visits or total recommended visits were near zero (total visits, $r = 0.06$; total recommended visits, $r = 0.09$).

Since the Cochran and Bartlett-Box tests demonstrated homogeneity of variance for the attendance compliance ratio with groups of unequal sizes, analysis of variance was used to determine that there were significant group differences. Table 4 shows the summary table for the analysis of variance with group means and standard deviations for attendance compliance ratios.

Discussion

Sample Selection Bias

In this study it was proposed that prior compliance with recommendations about follow-up appointments would be greater among participants in a study on non-compliance than among nonparticipants.

TABLE 4. Analysis of Variance Summary Table
Attendance Compliance by Group

Source	DF	Sum of Squares	Mean Squares	F	Probability
Between groups	5	0.8163	0.1633	2.33	<0.05
Within groups	161	11.2988	0.0702		
Total	166	12.1151			

Group	N	Mean Attendance Compliance	Standard Deviation
Hypertensive-nonparticipant noncompleters	25	0.5578	0.3019
Unknown-nonparticipant	40	0.6116	0.2523
Hypertensive-nonattender	13	0.6410	0.2819
Hypertensive-participant	40	0.6750	0.2805
Normotensive-participant	40	0.7546	0.2253
Hypertensive-nonparticipant completers	9	0.7611	0.2804

The data indicate that different rates of attendance compliance exist for participants and nonparticipants. Participants fell in the upper range of attendance compliance, and, in general, nonparticipants had past attendance compliance rates in the lower range.

The interpretation of the finding in this study of a biased sample depends in large part upon the extent to which one is willing to assume that attendance compliance predicts compliance for other medical recommendations. Based on the literature, compliance for one recommendation does not predict behavior for other recommendations. Two points argue against the literature. One is that the patient who does not attend will not have the opportunity to receive the medical recommendations associated with the study: nonattendance is therefore maximum noncompliance in this situation. The second is that there is reason to question earlier findings of low correlations among different regimens on the basis of demonstrated biased samples found in this study. Reported weak correlation coefficients between any two regimens may be a statistical consequence of using a restricted range of compliant behavior (as found among participants). The

relationship may be stronger when data from the nonparticipants are included.

Therefore, the present study interprets the results to indicate that participants in an investigation of medical compliance are generally more compliant than those who choose not to participate. As a consequence, participants may have a tendency to comply with other medical recommendations, a tendency that may not be evident among nonparticipants.

Research outcomes of past studies may not apply to nonparticipants. Rates of noncompliance or factors associated with noncompliance may be underestimated. Various strategies or techniques that have been investigated to determine the effect on compliance may have a different effect on those not included in the study.

Several points should be made about this study. First, attendance compliance of the hypertensive-nonparticipant completers was in the upper range and, therefore, appears to deviate from the overall pattern. Patients in this group declined treatment in the Hypertension Clinic and indicated that they would seek treatment from another source. Their nonacceptance of treatment in the Hypertension Clinic may reflect a preference for an alternative

treatment facility rather than noncompliant behavior per se, and further investigation is warranted. However, information was not available about whether treatment was actually sought.

It should be recognized that the present study has its own problems with sample selection bias, problems that tend to be common in other investigations. First, the population chosen for the study on compliance was narrow; it included individuals from one region, who were using hospital ambulatory facilities. Second, the study was select for disease; only hypertension was investigated. Finally, in order to find sufficient data on past attendance compliance in the present study, some patient records were excluded. From the comparison of eligible and ineligible patients, those included in this study came from a lower socioeconomic group and made greater use of health services.

However, differences in use of health services may have resulted from socioeconomic differences. The ineligible patients with their higher socioeconomic status may have sought most health care at suburban hospitals or in private physicians' offices. The hospital records would then contain less information about past medical history and social history, suggesting fewer health and social problems than may exist.

Regardless of the existence of differences in use of health services, the patients admitted to the study and the ineligible patients seem to differ on socioeconomic status, which may or may not be a factor in compliant behavior. Thus, any interpretation of findings in this study related to broad indicators of compliance should consider that our sample is socioeconomically select. However, as other compliance investigations have been conducted with similar samples, the results on sample bias can be generalized to other studies.

Conclusions

The purpose of this investigation was to determine if samples chosen for research on compliance consist of those who have a proclivity to comply. It was found that past compliance for recommended medical visits did vary across groups of participants and nonparticipants. Those who ultimately participated in a compliance study had past attendance compliance rates falling in the upper range. The results of investigations using similar volunteer samples should be generalized only to those who would participate in a compliance study.

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Health Diaries: Strategies for Compliance and Relation to Other Measures

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This article describes experience with the use of health diaries in a two-year prospective study of the influence of the psychosocial environment on the health status of 500 subjects in the Hamilton area. Three strategies were used to maintain compliance: 1) random sampling of three days within each two-week interval; 2) a lottery ticket incentive; and 3) telephone follow-up. The results of an initial telephone and lottery ticket study demonstrated a significant effect on compliance. The data from the two-year study were analyzed to characterize health change based on diary reports over successive six-month intervals and to determine the relationship of reported health to medical utilization data. The results indicated that subjects reported symptoms on about one third of the days surveyed but took no action on about one third of these symptom days. Only one quarter of the symptom days resulted in a change in usual activity, and fewer than one tenth of the symptom days resulted in time off from work or physician visits. The diary variables showed a low, positive correlation with health utilization.

ANY ATTEMPT TO STUDY the factors that influence health and disease in a general population must deal with the issue of measuring episodes of illness. The most readily accessible measures of illness—hospital or ambulatory records—represent only a small fraction of the illness actually experienced by individuals, as pointed out by White¹ in his classic paper. Utilization data can be supplemented by personal interviews, but the cost of such an approach precludes its use on a regular basis, as does the finding that subjects have limited recall for health problems over a time interval of weeks or months.²

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One alternative that has been used to a limited degree for several decades is the health diary—a personal, day-by-day record of health-related events completed by patients over a period of weeks or months. Verbrugge³ has recently reviewed studies using health diaries reported in the literature from 1940 to the present. Of the 19 studies cited, only seven used the diary as the primary source of health data. The remainder used the diary either as a methodological check on other measures of health or as a reminder during subsequent interviews. Two of the seven studies, both conducted in the early 1950s, used diaries over an extended time—from one to ten years. None of the recent studies has attempted to extend the diary period beyond four to six weeks.

There appears to be good reason to limit the total duration of diary usage. Although initial compliance appears to be relatively

high among those who consent to participate, there is a consistent drop in the reporting of illness with the passage of time, amounting from 5-25 per cent over a three-month period. Mooney⁴ has attributed this to "fatigue," a lack of willingness to complete the diaries in the same detail as time passes.

Thus, although the diary has some very attractive features, principally its ability to tap into mild or acute episodes of illness that would not be reported to a physician, it has been used infrequently in longitudinal studies, apparently because of a decline in both participation and completeness over time.

Methods and Materials

The present article reports on the use of a diary as one source of health data from a large sample of patients in a longitudinal study to assess the influence of the psychosocial environment on health status.

This prospective study involved a cohort of 518 adult patients, randomly sampled from ten family practices in the Hamilton region. Subjects were followed over a two-year period, using a variety of data sources including a home interview completed upon entry into the study and at six-month intervals, documentation of physician contacts using an encounter form and the health diary, completed for three days every two weeks.

The study had two hypotheses:

1. The positive relationship between recent stressful events and illness will be modified by personal coping resources. Effective coping resources will weaken the relationship, whereas ineffective personal coping will strengthen it.
2. The positive relationship between recent stressful events and illness will be modified by support from the social network. The stronger such support, the weaker will be the relationship.

To test the hypotheses a more sensitive measure of change in health than physician visits was required, in view of the fact that this population had approximately one

visit per subject in a six-month interval. For this reason, a health diary, allowing sampling of health status at two-week intervals, was included in the study.

The personal interview contained a number of standard scales: the Recent Life Change Questionnaire of Holmes and Rahe,⁵ Rotter's Locus of Control Scale,⁶ the Multidimensional Health Locus of Control,⁷ a scale of health values,⁸ a scale developed by the investigators to assess support available from social relationships,⁹ and Langner's scale of physiological and psychological symptoms.¹⁰

The design and methods of the study are described in more detail elsewhere.¹¹ The purpose of the present article is to examine the use of the health diary: methods of administration, data on compliance and reported symptoms, and relationships to other measures of illness.

Methods of Administration

At the time of the initial home interview, subjects were informed about the diary by the interviewer. The first set of diaries was mailed out within two weeks, and thereafter a set of diaries was mailed out every two weeks to be completed for three consecutive days, selected at random by the research team. The choice of a random three-day period was made for a number of reasons:

1. By confining the diary period to a three-day sample every two weeks, we felt that we could obtain adequate documentation of the change in the subject's health over the duration of the study without major inconvenience to the subjects.
2. The random selection of the diary days insured that the sampled days would be a random sample of individual health and would also provide a small degree of novelty. The sampling of days was conducted so that for each individual, and for the sample, each day of the week was sampled uniformly.
3. Subjects were asked to complete the diary for the three days at one sitting, on the last day of the diary period. We felt this would reduce the work load of subjects, but

would not seriously affect their ability to recall information.

Within 48 hours of the scheduled day of completion of the diary, subjects were contacted by phone and asked if they had completed and returned the diaries. The telephone follow-up was conducted for all subjects.

Finally, as an incentive, a provincial lottery ticket, costing one dollar, was mailed to subjects after every three diary periods (six weeks), regardless of whether diaries had been completed or not. Ideally, we would have preferred to have telephone follow-up only when diaries were not returned, as the telephone calls became a minor irritation to some subjects, but this was not possible because of logistics. Similarly, it would have been preferable to send a lottery ticket only for completed diaries, but this would have added considerably to the logistical problems of the study.

Information about each day in the diary period was documented on a separate page. The variables assessed included reported symptoms and their subjective severity rating, actions taken (time off from work, health professional visit, prescription or over-the-counter medication, etc.), and an overall rating of health on a five-point scale. The diaries were sent with a stamped, self-addressed envelope for return mailing.

The data were keypunched and entered into a summary patient file through an input program that developed a number of summary variables over each six-month period between interviews.

Diary Compliance—Pilot Study Results

As already described, two incentives were incorporated into the diary administration in this study: telephone encouragement at the end of each diary period and a lottery ticket sent to each individual at the end of every three diary periods. Because these techniques add to the cost of acquiring the diary data, they were initially

tested on a pilot sample of subjects ($n = 117$) drawn six months prior to the commencement of the main study. The 117 patients were randomly assigned to six groups of approximately equal size. Three groups received a lottery ticket every two months, and three did not. Crossed with this factor, two groups received a telephone reminder; two, a mailed reminder; and two, no reminder. The percentage of diaries returned in each cell is shown in Table 1. There is considerable variability in compliance, ranging from a high of 93% in the lottery-telephone reminder group to a low of 52 per cent in the no-lottery-mail-reminder group. Apparently, the mailed reminder had no, or a negative, effect on diary returns; by contrast, the telephone reminder increased compliance from 11 to 16 per cent. The lottery ticket had a similar effect on compliance.

Based on the results of this pilot study, both telephone reminder and the lottery ticket were incorporated in the main study.

Compliance Over Two Years— Main Study Results

Six months after the start of the pilot study, the remaining 401 subjects entered the study. Because subjects were followed for 24 months after the initiation of the pilot study, diary information is available for 24

TABLE 1. Pretest Results—Compliance With Different Reminders and Incentives (Diaries Returned/Diaries Sent)

	Lottery Ticket		Average
	Yes	No	
Phone	93% $n = 18$	74% $n = 21$	83%
Reminder card	80% $n = 18$	52% $n = 18$	67%
None	72% $n = 20$	72% $n = 22$	72%
Average	81%	67%	

$$\chi^2 = 17.91 \text{ } p < 0.001.$$

months on the initial pretest sample of 117 subjects, and for 18 months on the remaining 401 subjects. One further experimental manoeuvre, the discontinuation of the telephone reminder, was introduced after 18 months. This decision was taken because there was some indication that subjects were irritated by the repeated telephone reminders. As a result, while the pretest sample was followed for four six-month intervals, they received telephone reminders for the first three intervals but did not in the last six-month interval. The main study sample was followed for 18 months, with telephone reminders during the first 12 months.

At the completion of each six-month period, some individuals refused to be reinterviewed. Six months after the initial interview, 59 (11 per cent) dropped out, and a further 31 individuals (6 per cent) did not complete a third interview. Of the original 117 individuals in the pilot study, 34 (29 per cent) had dropped out by the time of the fourth interview.

Diary compliance was calculated in each six-month sequence for those individuals who consented to be interviewed at the start of the time period. The compliance rates are shown in Table 2. Those rates remained nearly constant over the first 18 months of the study. The deletion of telephone follow-up resulted in a statistically significant drop in compliance of about 5 per cent [$\chi^2 = 40.15$, $p < 0.0001$]. Although significant, the reduced com-

pliance is much less than that which would have been anticipated from the pretest results if telephone reminders had not been implemented at the beginning of the study.

These average values may obscure a wide range in behavior of individual subjects, however. To approach this question, subjects in each time period were categorized into those who had returned fewer than 25 per cent of the diaries, 26–50 per cent, 51–75 per cent, 76–99 per cent, or 100 per cent of the diaries. These data have remained constant over the three time periods, with slightly more than half the subjects returning all diaries and about 80 per cent of subjects returning more than 75 per cent of the diaries. A drop of approximately 2 per cent in the number of subjects returning more than 75 per cent of the diaries was noted when telephone reminders were discontinued.

Further analysis was conducted to determine whether there was any identifiable difference in sociodemographic variables between compliant and non-compliant subjects. The 422 subjects who completed more than 75 per cent of diaries in the first time period were contrasted with the 96 remaining subjects.

Compliant subjects were older (41.4 vs 36.6 years, $t = 3.89$, $p < 0.0001$), and slightly more of the compliant subjects were married [84 per cent vs 76 per cent, $\chi^2 = 7.5$, $p < 0.01$]. Educational level, sex, income and socioeconomic status did not differ between the two groups.

TABLE 2. Diary Compliance Over Four Six-Month Time Intervals

Time Period	Telephone Reminder	Number of Subjects	Number of Diaries		Compliance
			Sent	Received	
0–6 months	Yes	518	6031	5137	85.2%
7–12 months	Yes	459	6056	5281	87.2%
13–18 months	Yes	92	1192	1024	85.9%
	No	336	4351	3603	82.8%
19–24 months	No	83	1078	878	81.4%

χ^2 phone–no phone = 40.15; $p < 0.0001$.

Dimensions of Health Reported From Diaries

The diary data over the four time periods were analyzed to characterize the dimensions of health revealed by the diaries and to determine the relation between health reporting, compliance and seasonality. Mean values of a number of diary variables in each time period are shown in Table 3. On the average, subjects returned diaries covering from 30 to 34 days within each six-month period. At least one symptom was reported for approximately one third of these days. There is some evidence of a fall off in reporting, amounting to about 12 per cent per year. On those days when symptoms were reported, about 1.5 symptoms were mentioned, with an average severity of 2.6 on a five-point scale.

Although patients reported symptoms on about one day in three, they took action about their symptoms on about two thirds of the days when symptoms were reported. Some activity change was reported for 2.4-2.8 days in each time period, roughly one quarter of those days in which symptoms were reported. Relatively few of

the reported symptoms were sufficiently severe to result in time off from work (0.4-0.5 days per period), and few symptoms resulted in a health professional contact (0.5-0.6 days). Overall, patients reported an average health evaluation of 4.8 to 5.4 on a seven-point scale. Not surprisingly, the correlations among these variables are high, ranging from 0.4-0.8.

Although the compliance with diary returns was high, it is of interest to determine whether the results were biased by non-returns. Two sources of bias could potentially influence the results: 1) individuals who return only a portion of the diaries in any time interval may show different patterns of health from those who return all diaries, and 2) approximately, 5-10 per cent of subjects refused to be reinterviewed after each time period. If these individuals were less healthy than those who were interviewed, this may account for the apparent improvement in the health measures of Table 3 over successive six-month intervals.

The effect of nonreturns within a time period was addressed using the two groups designated above. Those individuals who

TABLE 3. Mean Values of Diary Variables over Four Six-Month Time Sequences

	Sequence I	Sequence II	Sequence III	Sequence IV	Significance
Sample size	518	459	428	83	
Average number of diaries sent	34.93	39.58	38.85	38.96	
Average number of diaries	29.96	34.42	34.19	34.51	<0.0001
Number of days with symptoms	10.8	10.5	9.3	9.1	0.06
Per cent of days with symptoms	0.36	0.28	0.27	0.26	<0.0001
Number of symptoms per symptom day	1.46	1.40	1.47	1.51	NS
Average severity (5 = point scale)	2.67	2.69	2.66	2.65	NS
Number of days with action	6.99	6.58	5.89	6.04	NS
Number of days with activity change	2.51	2.46	2.40	2.83	NS
Number of days with health professional contact	0.62	0.66	0.59	0.58	NS
Number of days off from work	0.58	0.49	0.56	0.42	NS
Average health evaluation (7 = point scale)	4.81	5.45	5.44	5.37	<0.0001

returned more than 75 per cent of diaries were designated the "compliant" group, and individuals returning 75 per cent of fewer diaries were designated a "non-compliant" group. The compliant group returned an average of 33.8 diaries in the first sequence, 96 per cent of those sent. By contrast, the noncompliant group returned 11.9 diaries on the average, a return rate of 36 per cent. The noncompliant subjects naturally reported fewer symptoms and actions overall; the proportion of reported days with symptoms, activity change, time off from work and health professional contact, however, did not differ between the two groups. Thus, compliance with diary returns does not appear to influence subjective perception of health, and the information received from relatively non-compliant subjects may be a valid sample of their perceived health.

To determine if dropouts from the study resulted in a bias, the analysis of Table 3 was repeated using only the 428 subjects who remained in the study over all three sequences. The data were similar to those of Table 3—in particular, a similar trend to lower reporting of health-related behavior over time was noted. This trend is therefore likely due to the fall-off effect described by Mooney,⁴ rather than to a selective dropout of less healthy individuals from the sample.

The data on reported symptoms and actions were also analyzed by calendar month over the two-year duration of the study. The proportion of reported diary days with symptoms and action showed similar trends over time. A seasonal effect was present, with a sharp minimum in June, July and August of each year, during which approximately 20–25 per cent of days had reported symptoms and about 15 per cent resulted in some action. These variables rose to a maximum of about 45 per cent symptom days and 25 per cent of days with action in the fall months, followed by a gradual decline over the winter and spring months.

Relationship between Diary and Other Health Measures

To examine the relationship between measures of health obtained from the diary and other measures of health and illness used in the study, selected diary variables were correlated with 1) the number of symptoms obtained from the Langner scale administered at each interview and 2) number of visits to a family physician. The Langner scale of subjective distress has frequently been used in the literature as a measure of the effect of stress on individuals and was found in the present study to be very stable over time ($r = 0.85$ over successive time sequences).

Most of the diary variables show a moderate correlation with the Langner score, ranging from 0.20 to 0.35. The number of days off from work and the number of days with a health professional contact exhibit much lower correlations; however, the distribution of these two variables is highly skewed, with 68–80 per cent of patients reporting no events in these categories.

The other measure of health available is the number of encounters with the patient's family physician. In contrast to health professional contacts reported in the diary, these data were obtained directly from the subject's family physician using a brief encounter form designed for the study. The number of encounters was highly skewed, with 55 per cent of patients reporting no encounters in a six-month period. As a result, the correlations between the diary variables and physician utilization ranged between 0.14 and 0.26, with the best correlation being between the reported number of diary days with health professional contact and the number of family physician visits. Because the reported health professional contacts from the diary represent only a sample of family physician visits (on those days sampled by the diary) and cover visits to all health professionals, this low correlation is not too surprising.

Conclusions

The health diaries used in the present study have served a useful role in measuring perceived morbidity in a large sample over an extended time period. The use of several strategies—time sampling at random intervals, lottery tickets and telephone reminders—maintained high compliance over the duration of the study and reduced the conditioning effect to a reasonable level, resulting in fewer reported symptoms.

The data obtained from the diaries result in a dramatically different perspective on health and illness than that obtained from physician utilization data. Although subjects visited a family physician only once, on the average, in a six-month interval, and half the sample reported no visits in each time period, they reported symptoms on about one day in three. Apparently, most of the reported symptoms are minor, since about one third of the days with symptoms resulted in no action being taken by the subject. Some activity change was reported for about 25 per cent of the symptom days, but less than one day of the 30 days sampled in each time period resulted in time off from work or a physician visit. Variables derived from the diary reports showed a moderate correlation with a symptom scale administered at the time of the home interview and a low correlation with visits to the family physician.

Apparently, the health diaries represent a sensitive measure of a dimension of illness that could not be assessed by other means. In terms of the major objectives of the study, it remains to be shown whether

aspects of the psychosocial environment, life stress, and social personality variables are more directly related to the frequent occurrence of minor illness documented by the health diary, or to the more severe episodes of illness that are brought to the family physician.

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Patient Characteristics That Influence Physician Behavior

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We examined whether four patient characteristics (age, ethnicity, sex and appearance) influenced five physician behaviors with the patient (interviewing, nonverbal attention, courtesy, information giving and empathy). Ten physician-patient interactions were observed through a one-way mirror for each of 15 physicians. Physicians were rated higher on information giving ($p = 0.002$) and empathic skills ($p = 0.02$) when they were with female patients; on interviewing ($p = 0.02$) and empathy ($p = 0.0007$) with Anglo-American compared with Spanish-American patients; on interviewing ($p = 0.01$), nonverbal attention ($p = 0.001$) and courtesy ($p = 0.02$) when with the best groomed patients; and on courtesy ($p = 0.03$) with elderly patients. In addition, there were fewer physician-initiated interruptions with female patients ($p = 0.03$) and with well-groomed patients ($p = 0.02$). Each of the four patient characteristics studied acted independently in influencing physician behavior. The recognition that patient characteristics influence physician behavior should stimulate physicians to examine their reactions in order to insure that all types of patients receive thorough, courteous and empathic care.

LITTLE HAS BEEN DOCUMENTED about how a patient's attributes or characteristics directly affect a physician's behavior. This paucity of research reflects a medical ideal that all patients should be treated equally. "The physician should see to it that the patient's sentiments do not act upon his sentiments and, above all, do not thereby modify his behavior . . ."¹ Despite

twentieth-century research showing that physician-patient interactions function according to the same rules as do other social systems,²⁻⁴ the ideal persists. In 1968, when 132 physicians were asked about their behavior with patients, 80 per cent stated that they "gave the same amount of attention to all patients."⁵ More accurate and less idealistic perceptions of how physicians react to patient characteristics may allow the physician to improve patient compliance and to identify patients' problems more realistically.

Recently there has been increasing interest in several areas of patient-physician interaction.^{6,7} Eisenberg points out that most of the work in the field suffers from lack of case-controlled data and from an excess of opinion over fact.⁸ Nevertheless, some investigations have been well

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controlled. The few studies that have focused on the effects of patient characteristics on medical care have used such indirect measures of physician behavior as number of medications, referral to specialists, number of operations performed, or whether a physician's assistant or a physician is the primary caretaker. For example, Penchansky and Fox reported that primary physicians in group practice referred white patients to consultants more frequently than black patients.⁹ Egbert and Rothman found that blacks were two to four times as likely as whites to have surgery performed by a resident rather than a staff surgeon, and this difference remained when diagnosis and mode of payment were controlled for.¹⁰ Medicaid recipients were also at higher risk for receiving care by physicians in training. Perkoff and Anderson studied ward versus private patient status for patients visiting an emergency room and found that black patients with similar medical insurance were more likely than whites to be admitted to ward status and that whites were more likely to be admitted to the hospital than blacks with similar chief complaints.¹¹ Other studies suggest that socioeconomic status affects how a patient is treated. The higher a patient's socioeconomic status, the more likely he/she is to be seen by a physician rather than paramedical personnel,¹² the more consultations are made, and the more likely he/she is to receive an appendectomy or tonsillectomy.¹³

In addition to race and socioeconomic status, some authors have postulated that certain types of patients might elicit negligent behavior from physicians. For example, articles by Lennare and Lennare¹⁴ and Howell¹⁵ allege that women are treated differently than men on the basis of sexual prejudice. Papper simply states that aged, dirty and ungrateful patients are undesirable to treat and may receive inferior care.¹⁶ Duff and Hollingshead concluded that a patient's physical appearance influences

medical care⁴ and Baldigo et al. have shown that medical students attribute negative characteristics to obese patients.¹⁷ Crane emphasizes the importance of the physician's individual reaction to the patient's disease in determining the course of treatment.¹⁸

Our study examines how the characteristics of the patient affect the behavior of the physician. We did not look at end points or outcome; we looked directly at physician behaviors during the patient-physician interaction. The patient attributes we chose to study were age, ethnicity, sex and neatness of appearance. These are all attributes routinely noted in the first sentence of the medical history. The physician behaviors assessed were information giving, interviewing, empathy, nonverbal attention and courtesy. We found marked differences in these physician behaviors depending on characteristics of the patient.

Method

Subjects

This study was conducted in the outpatient clinic of a university teaching hospital. Fifteen unselected residents in their second and third year of medical training were studied in their weekly outpatient clinics. All physicians approached agreed to participate in the study. One hundred fifty physician-patient interactions (ten per physician) were evaluated through a one-way mirror by a trained observer over a three-month period. We approached 162 patients, and 150 agreed to participate. Written informed consent was obtained from both the patient and the physician. All 15 physicians were of Anglo-American (non-Hispanic white) ethnic origin; four were female. One hundred seven of the patients were female, and 43 were male. Sixty-seven patients were of Anglo-American origin, 74 were Spanish-American, three were American Indian and six were black. All of the study popula-

tion spoke English. Mean patient age was 57.5 years; all physicians were between 25 and 35 years of age.

Observations

Each of 28 physician behaviors was rated on a four-point scale and subsequently grouped for analysis into five categories as described in the results section of this article.¹⁰ Physician behaviors rated included such skills as listening, information giving, use of humor, empathy, etc. If a skill was not observed, no rating was recorded for that skill, and it was treated statistically as a missing value. For example, use of humor by the physician and/or patient was rated for its appropriateness and effectiveness. Use of light humor that helped put the patient at ease would receive a favorable rating, whereas a physician's joking response to a patient's expression of fear toward an upcoming procedure would receive an unfavorable rating. If neither the patient nor the physician initiated any humor, no score was recorded. Observer variability was assessed by having two observers rate the same interactions independently and comparing the ratings. In 122 of 130 ratings (94 per cent), the two observers did not differ or differed by only one point in scoring the physician behavior. Data collected in addition to the 28 behaviors include patient age, total patient time with physician, number of physician-initiated interruptions (when the physician left the room), and sex and ethnicity for both the patient and physician. Physical appearance was also rated on a four-point scale. A rating of 4 would describe someone who was "clean and pressed" in a three-piece suit or attractive dress, hair clean and neatly styled. A rating of 1 would describe an individual with rumpled and dirty clothing who was generally disheveled.

Statistical Analysis

All variables were keypunched directly onto IBM cards from the observation

forms. Data were analyzed using Statistical Analysis System (SAS) version 79.2B, and Biomedical Data Processing (BMDP) on an IBM 3032 computer. Inferential analysis was done using Student's *t*-test for comparing two groups, one-way analysis of variance for comparing more than two groups, and a log-linear model for analysis of variance of categorical data to test for interrelationships among variables.

Results

The ratings of 28 physician behaviors were grouped into five categories. "Information giving" assessed the effectiveness of the physician in communicating verbally, clarifying, summarizing and talking at the patient's level. "Interviewing" included such skills as using open-ended questions, eliciting details and allowing the patient an opportunity to ask questions. "Empathy" addressed the physician's ability to acknowledge the patient's prominent feelings, to pick up on the patient's mood changes (for example, if a patient's behavior were to change from loquacious to quiet with closed body language), and to acknowledge the patient's emotional needs. "Nonverbal attention" included eye contact and the physician's position in relation to the patient. "Courtesy" assessed the physician's formal greeting of the patient and formal closure of the interaction.

The mean ratings for the observed physician behaviors are listed in Table 1. Nonverbal attention to the patient, as well as interviewing skills, were rated uniformly high. Skills with intermediate ratings included information giving and courtesy. With regard to courtesy, greetings were rated higher than closures (3.2 ± 0.05 vs 2.8 ± 0.08 , mean $\pm$ SEM, $p < 0.01$).

In general, the ratings for empathic skills, such as picking up on the patient's mood changes and acknowledging the patient's feelings and emotional needs, were lowest. Two other areas with low scores were the use of humor and touching.

Humor was often used inappropriately and was seen primarily as a release from tension when either the patient or physician was uncomfortable. Some physicians touched patients as a comforting gesture, but not all patients were comfortable receiving this touching. Some patients appeared eager for a comforting gesture from the physician, but not all physicians perceived this cue or were able to respond to it.

Physician Behavior and Patient's Sex

As shown in Table 2, ratings of information giving and empathy were significantly higher with female patients than with male patients, while there were no differences in the ratings of interviewing, nonverbal attention or courtesy toward male and female patients. In addition, physician-initiated interruptions were significantly less frequent with female patients.

Physician Behavior and Patient Ethnicity

As shown in Table 3, the ratings of interviewing and empathy behaviors were significantly higher with Anglo-American than with Spanish-American patients. In addition, there was a trend for the physician to spend more time with the Anglo-American than with the Spanish-American patient ($p = 0.07$). Thus, ratings of physician skills that involve receiving and perceiving communications by the patients (interviewing and empathy) were significantly lower with the Spanish-American patients, while those of communicative skills not requiring the sensitive processing of the patient's input (nonverbal attention, courtesy, information giving) were not significantly different. Our feeling was that the Anglo-American physician and Spanish-American patients attempted to communicate with each other, but the communication was not fully received by either party. It should be emphasized that all the Spanish-American patients spoke English; however, for most of these pa-

TABLE 1. Mean Rating of Physician Behaviors by the Observer

Observations	Rating *
Interviewing	3.5 $\pm$ 0.7
Attention	3.4 $\pm$ 0.7
Courtesy	3.2 $\pm$ 0.7
Information giving	3.0 $\pm$ 1.0
Empathy	2.0 $\pm$ 1.1
Physician-initiated interruptions	0.5 $\pm$ 0.8
Time of interaction	16.4 $\pm$ 8.6
Patient appearance	3.2 $\pm$ 0.9

* Data given as mean $\pm$ SD for 150 physician-patient interactions.

tients Spanish was the primary language used in the family.

Physician Behavior and Patient Appearance

The two lowest scores for patient appearance were combined into one for analysis. As shown in Fig. 1, all ratings improved as the patient's appearance improved. For three ratings (interviewing, nonverbal attention and courtesy) this difference was statistically significant. There were also fewer physician-initiated interruptions with the patients rated highest on appearance ($p = 0.02$). There was no difference in total time of the physician-patient interaction as a function of patient appearance ($p > 0.5$).

TABLE 2. Physician Behaviors With Male and Female Patients

Observations	Female Patients (106)	Male Patients (42)
Interviewing	3.5 $\pm$ 0.6*	3.4 $\pm$ 0.7
Attention	3.4 $\pm$ 0.7	3.3 $\pm$ 0.7
Courtesy	3.2 $\pm$ 0.7	3.3 $\pm$ 0.7
Information giving	3.1 $\pm$ 0.9†	2.5 $\pm$ 1.0
Empathy	2.2 $\pm$ 1.1†	1.7 $\pm$ 0.9
Physician-initiated interruptions	0.4 $\pm$ 0.8‡	0.7 $\pm$ 0.8
Time of interaction	16.4 $\pm$ 9.1	17.3 $\pm$ 7.8

* Data given as mean $\pm$ SD.

† Different from male patients, $p = 0.002$.

‡ Different from male patients, $p < 0.03$.

TABLE 3. Physician Behavior With Anglo-American and Spanish-American Patients

Observations	Anglo-American Patients (67)	Spanish-American Patients (74)
Interviewing	3.6 $\pm$ 0.6*†	3.3 $\pm$ 0.7
Attention	3.4 $\pm$ 0.7	3.3 $\pm$ 0.7
Courtesy	3.2 $\pm$ 0.7	3.1 $\pm$ 0.7
Information giving	3.0 $\pm$ 0.9	2.8 $\pm$ 1.0
Empathy	2.4 $\pm$ 1.0†	1.7 $\pm$ 1.1
Physician-initiated interruptions	0.6 $\pm$ 0.9	0.4 $\pm$ 0.7
Time of interaction	18.0 $\pm$ 10.2	15.3 $\pm$ 7.1

* Data given as mean $\pm$ SD.

† Different from Spanish-American patients, $p = 0.02$.

‡ Different from Spanish-American patients, $p < 0.001$.

Physician Behavior and Patient Age

Patients were divided into four age groups, under 45, 45–64, 65–74 and over 74

years of age. As shown in Fig. 2, there were no changes in ratings of physician behaviors with the age of the patients except for those patients over age 74, when all

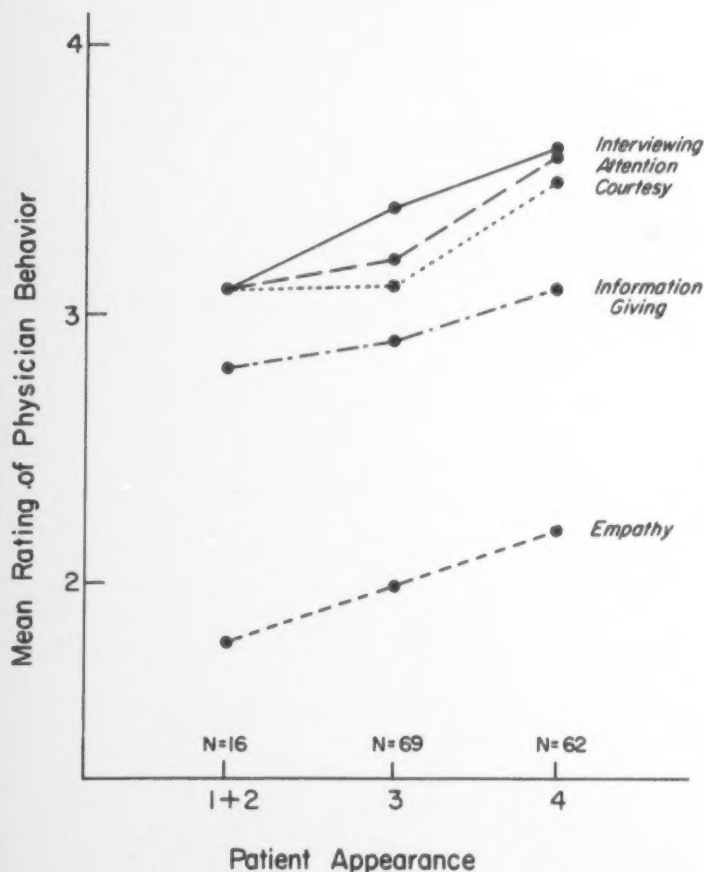


FIG. 1. Physician behaviors as a function of patient appearance. As patient appearance improved, physicians were rated significantly higher at interviewing ($p < 0.01$), attention ($p < 0.001$) and courtesy ($p < 0.02$) skills. The ratings for information giving and empathy did not vary significantly with patient appearance ($p > 0.4$). Data were analyzed by one-way analysis of variance.

ratings of physician behaviors tended to improve. The increased ratings with these elderly patients were significant only for courtesy ($p = 0.03$).

When the patient population was divided at age 40, there were two significant differences. More time was spent ($p = 0.003$), and ratings of information giving increased ($p = 0.01$) with the older population.

Independence of Patient Characteristics in Influencing Physician Behavior

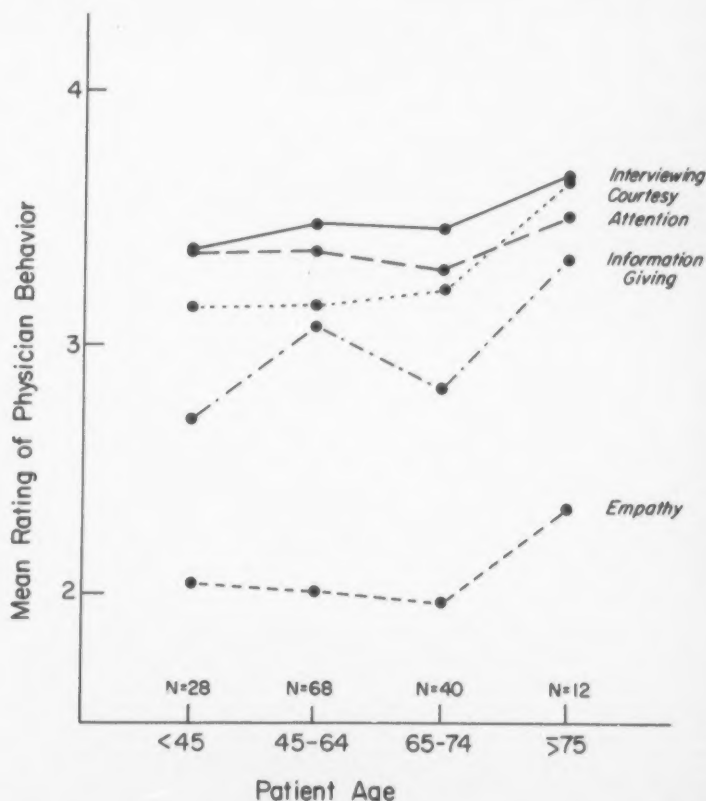
Because we found significant differences in our ratings of some physician behaviors as a function of the patients' sex, ethnicity, appearance and age, we tested for interrelationships among these patient characteristics. For example, we asked whether ratings of physician cour-

tesy, which were significantly higher for patients over the age of 75, could have been due to an increased number of female, Anglo-American and/or neat appearing individuals in this age group. Using a log-linear model for analysis of variance of categorical data, we found that there were no significant interrelationships ($p > 0.40$ for each of the 90 possible interrelationships). This suggests that each of the patient characteristics that we measured acted independently in influencing the ratings of physician behavior.

Discussion

The results of this study are that ratings of physician behaviors, made by a trained observer, varied with the sex, age, appearance and ethnicity of the patient. Physicians were rated significantly higher on in-

FIG. 2. Physician behavior as a function of patient age. Ratings of all behaviors tended to increase in patients over the age of 75. This difference was significant only for the ratings of courtesy ($p = 0.03$).



formation giving and empathy when they were dealing with female patients; on interviewing and empathy with Anglo-American patients; on interviewing, attention and courtesy when with the best groomed patients; and on courtesy with elderly patients. Although we did show a high degree of interobserver reliability, we have not ruled out the possibility of observer bias due to shared perceptions. For example, the two observers may share the perception that older patients are treated "better" or that Spanish-American patients are discriminated against. The fact that the objective data collected (time of interview and number of physician-initiated interruptions) supported the subjective data would tend to strengthen our overall findings.

The four patient characteristics all acted independently in influencing physician behavior. Each characteristic influenced physician behavior to the same extent before and after we controlled for the effects of the other patient characteristics. On the whole, then, well-groomed, elderly Anglo-American women received the highest rated physician behaviors, while disheveled, young Spanish-American males received the lowest rated behaviors. It is still possible, however, that the various influences on physician behavior by the four patient characteristics were mediated in part by other characteristics that were not examined in this study as, for example, the patient's diagnosis or educational status.

Our findings on changes in ratings of physician behavior with the sex of the patient appear to disagree with the widely publicized view that medical care is given in a way that disparages women.^{15,20} We found that physicians were rated significantly higher in information giving and empathy with female than with male patients. In addition, physicians left the room during the interview significantly fewer times with female patients. These data are

in accord with those of Keskiner et al. who found that female patients were more likely to be referred to a psychiatrist than were male patients with the same symptoms of neurosis;²¹ in both studies possible sexist attitudes of the physicians would appear to work in favor of better medical care for female patients.

The decreased rating of physician interviewing and empathy skills with Spanish-American patients was expected and, to some extent, unavoidable. Intimate communication across a cultural barrier is more difficult than within the same culture, even when both individuals speak the same language.^{22,23}

The generally low rating for empathetic skills with all patients supports Duffy's data showing that one of the least frequently used skills by physicians is the ability to ascertain patient emotions and that physicians are least comfortable speaking about psychosocial problems.²⁴

It should be emphasized that the fact that we found differences in ratings of physician behavior with the different types of patients does not necessarily prove that these differences represent inappropriate behavior by the physicians studied. The purpose, after all, of the patient's visit to the physician is the provision of medical care, not an exercise in courtesy, communication or empathy. In addition, the changes in ratings of physician behavior could result from the physician's perceptions of the patient's expectations. For example, the increased rating of courtesy toward elderly patients could be seen as an appropriate response to the expectations of this group of patients. On the other hand, data from other studies and our own preliminary data show that such physician behaviors as courtesy, interviewing and information giving do correlate with patient satisfaction²⁵⁻²⁸ and with subsequent patient compliance with their medical regimens.²⁶⁻²⁸ Therefore, it is legitimate to ask whether the decrease in ratings of inter-

viewing skills when physicians were working with Spanish-American patients, for example, might contribute to poorer medical care for these individuals.

The concept that a physician's behavior is influenced by a particular characteristic of the patient has evolved in the past two decades from an initial position of outright denial. Until recently, medical students and physicians were simply told that it was wrong to let a patient's personal characteristics influence their behaviors.^{1,31} More recently it has become acceptable to recognize that extremes of patient characteristics and behavior do influence the physician. Thus, there has been a series of articles advising physicians on how to deal with "problem patients," "disliked patients" or "hateful patients."³²⁻³⁵ We have recently reported that patients with impaired mental status are disliked by their physicians, though the physicians were not consciously aware of this association.³⁶ In addition, we have shown that particularly stressful patients are at risk for punitive procedures such as inappropriate placebo use.³⁶

Many physicians are now willing to admit that certain types of patients (for example, alcoholics) give them trouble. We have attempted to take this one step further, to show that different patient characteristics, none of them "hateful," have a measurable influence on ratings of physician behavior. This observation should be obvious to sociologists, who have long recognized that all social interactions are bi-directional.³⁻⁴ In addition, psychiatrists since Freud have worked within the constructs of transference and countertransference, recognizing that particular characteristics of a patient can trigger unconscious conflicts in the physician and adversely affect the patient's psychotherapy.³⁷ Obvious though this may seem, medicine has managed to ignore, almost entirely, the fact that patient characteristics influence physician behavior. Recognition

by physicians that they behave differently with different types of patients can stimulate them to examine their reactions in an attempt to insure that all patients, regardless of age, sex, race and appearance, receive thorough, courteous and empathic medical care.

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Communications

Do Postcard Reminders Improve Influenza Vaccination Compliance?

A Prospective Trial of Different Postcard "Cues"

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A randomized trial of various postcard reminder "cues" was performed to improve understanding of health-related behavior and to find better strategies for improving influenza vaccination compliance. Data were gathered on 283 high-risk patients (92 per cent response rate) who received: 1) a "neutral" card simply announcing the availability of vaccine; 2) a "Health-Belief-Model" card written to take advantage of the association between certain health beliefs and vaccination behavior; 3) a "personal" card signed by the patient's physician; or 4) no postcard. The highest rate of vaccination occurred among recipients of the Health-Belief-Model postcard (51.5 per cent vs. 20.2 per cent for control, $p < 0.001$). Linear logistic regression analysis found that age, prior vaccination history and experimental group had a significant effect on likelihood of being vaccinated. After adjusting for age and prior vaccination experience, the vaccination rate was found to be significantly higher for persons receiving the Health-Belief-Model postcard compared with persons receiving no postcard or a neutral postcard. We conclude that reminder postcards emphasizing elements of the health belief model may help increase vaccination rates.

ANNUAL INFLUENZA IMMUNIZATION has been recommended since 1964 for persons over the age of 65 and for persons with chronic cardiac, pulmonary, renal and

metabolic diseases. Immunization is intended to prevent the excess mortality associated with influenza epidemics in this high-risk group.¹ However, overall vaccination rates among high-risk patients have been as low as 10 to 15 per cent according to the Center for Disease Control (CDC).²

These low rates have prompted us to study influenza vaccination to learn more about the general subject of health behavior and to find effective means to promote healthy behavior.³ Although research efforts over the years have used different constructs to explain the effects of personal, psychosocial and environmental elements on health and illness behavior,⁴⁻⁸ we chose to study the Health Belief Model (HBM) as formulated by Hochbaum, Becker, Rosenstock and others.⁸

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The HBM is a blend of social and psychologic theories, particularly value expectancy theory. The model predicts that an individual's perception of 1) susceptibility to a disease, 2) severity of the disease, and 3) benefits and costs of the action to prevent the disease will determine the likelihood of the individual undertaking that action. The HBM suggests two common determinants of impulses to action: 1) the value placed by an individual on a particular outcome or goal and 2) the individual's estimate of the likelihood that a particular action will produce the desired outcome.⁹

The model has been tested in a variety of settings involving symptomatic and asymptomatic health behaviors.¹⁰⁻¹⁴ Our initial study of influenza vaccination behavior during the 1975 vaccination period validated a variation of the HBM (Fig. 1), and showed positive correlations with compliance and the elements of the model.³ The study also demonstrated that a reminder postcard or "cue" was an effective means of promoting vaccination. Our study, like many others, was retrospective, but even in this retrospective study, the model explained a relatively small amount of variance.

Two more recent studies reported higher rates of correlation of the HBM with compliance in the Swine Flue immunization program. Using logit analysis of data collection retrospectively, Rundall and Wheeler¹⁵ reported that the HBM accounted for 34 per cent of the variance in the use of vaccine by senior citizens. Cummings et al.,¹⁶ in a prospective study of Swine Flu vaccination, explained more than 40 per cent of the variance with predictor variables, which included the HBM, measures of behavioral intention, social influence, physician's advice, socioeconomic status and past experience with flu shots. Path analysis revealed that most of the influence of HBM variables on behavior was mediated through behavioral

intention and that physician recommendations showed a substantial direct effect on vaccination behavior. Sackett¹⁷ has reported that, in contrast to retrospective studies, prospective studies of the HBM have shown inconsistent results. He believes these results to suggest that patients' health beliefs may result from, rather than cause, compliance. In the Canadian study of compliance with antihypertensive theory, beliefs changed to coincide with compliance: after six months of therapy, but not before, compliant patients perceived hypertension to be a more serious disease that benefited from drug therapy.¹⁸ The findings of Sackett^{17,18} and Cummings et al.,¹⁶ therefore, suggest that behavioral intent and subsequent behavior could be influenced by efforts directed at changing relevant health beliefs and support the rationale for our prospective trial of three postcard cues, each containing a different message (Fig. 1).

Postcard cues have been shown to lower broken appointment rates¹⁹⁻²¹ and have been retrospectively correlated with vaccination compliance.³ We reasoned that a postcard containing information emphasizing those health beliefs that correlated with vaccinations might be used to change behavioral intentions, thereby promoting vaccination compliance. We also wondered whether a postcard with a personal message from a patient's primary care physician might improve compliance because of the previously demonstrated effect of physician recommendations on health and vaccination behavior. Accordingly, we designed and executed a randomized prospective trial of the effect of cue postcards on vaccination behavior that compares vaccination rates of patients receiving a "neutral" postcard, an "HBM" postcard, a "personal" postcard, and no postcard. The purpose of the trial was to compare the effect of the HBM postcard with the effect of no postcard or a neutral postcard and to make similar comparisons

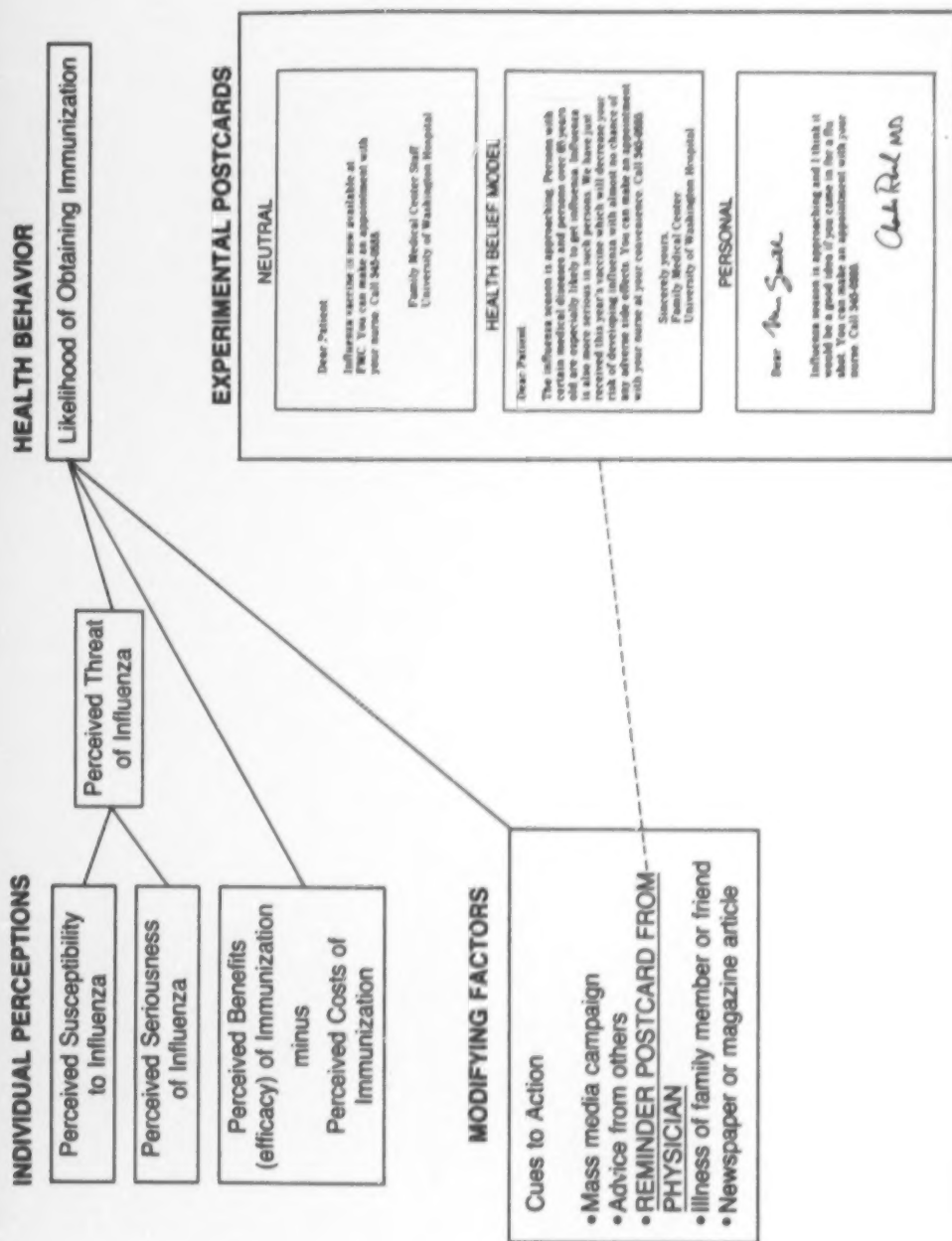


FIG. 1. "Health Belief Model" and experimental postcards.

for the personal postcard. The study also allows us to observe trends in influenza vaccination among outpatients following the national "Swine Flu" vaccination debacle of 1976, which we anticipated would lower overall vaccination rate.

Methods

The study was conducted at the University of Washington Family Medical Center (FMC). The study population consisted of those patients identified as being at high risk for serious complications from influenza infection¹: patients over 65 years of age and/or patients with chronic heart disease, bronchopulmonary disease, renal disease and diabetes mellitus, based on ICDA-8 diagnosis codes stored in the FMC's computer.

Three hundred ninety-five patients were identified and selected for study. These patients were randomly assigned to one of four groups: a control group receiving no postcard, a group receiving a neutral postcard, a group receiving an HBM postcard and a group receiving a personal postcard. When the 1978-1979 influenza vaccine became available, the postcards shown in Fig. 1 were mailed to patients. The HBM postcard obviously emphasizes the severity of influenza, the susceptibility of older persons to influenza and the benefits of vaccination. We did not intend to imply that older patients are more likely than younger patients to get influenza.

Initial demographic data were recorded when patients were assigned to experimental groups. Thereafter, data gathering occurred either when study patients came to the FMC for vaccination or in mid-December, when they were called and interviewed by phone. At that time, patients in the control group were called to determine if they had been vaccinated. They were also reminded of the availability of vaccine. Telephone interviewing was necessary because only 36.6 per cent of patients were vaccinated in the FMC.

Of 395 patients originally selected for study, 88 were unavailable for analysis because they had moved, died, were hospitalized, had withdrawn from the practice or had no phone. Of the remaining 307 patients, data were gathered on 283 (92 per cent response rate). Twenty-four could not be reached despite at least five phone calls, and one refused to be interviewed.

Statistical comparisons were made using Student's *t*-Test, chi-square Test or Fischer's Exact Test.²³ Linear logistic regression and the method of maximum likelihood²³ were used to adjust for the observed effect of age and prior vaccination status on vaccination rates.

Results

The patients were, as expected, an elderly and primarily female group. Mean age was 66.7 years (standard deviation, 16.4 years), and 67.7 per cent of the patients were female. The overall vaccination rate was 33.6 per cent, compared with a rate of 41.9 per cent for these patients in 1977-1978. Vaccination rates before the 1976 swine flu program had consistently been around 50 per cent.³

Only 36.6 per cent of patients were vaccinated at the FMC, and only 20.1 per cent of those vaccinated were vaccinated at a routine appointment. Other vaccination sites included the place of residence (19.6 per cent), the county Public Safety Building (9.7 per cent) and other sites including physicians' offices, fire stations, schools and work places (34.1 per cent). Patients vaccinated outside the FMC generally obtained vaccination free of charge. They were usually told of such options when they called the FMC for their appointment, which perhaps accounts for the high out-of-clinic vaccination rate.

Persons vaccinated had a greater mean age than persons not vaccinated (72.1 ± 10.1 years vs. 63.9 ± 18.2 ; $t = 4.09$, $p < 0.001$). Patients with pulmonary disease had a significantly lower ($p < 0.05$) vac-

nation rate (14.3 per cent) than patients with cardiac disease (41.0 per cent) or patients selected for study solely because they were over 65 years old (37.7 per cent). Vaccination rates slightly greater ($0.05 < p < 0.1$) for patients (high utilizers) with more than three clinic visits in the previous six months (41.5 per cent) compared with low utilizers (28.1 per cent), and for patients without a history of adverse reaction to influenza vaccine (50.0 per cent) compared with patients with an adverse reaction to influenza vaccine (31.7 per cent). Vaccination rates did not differ for males and females, or for persons with and without a past history of influenza.

Table 1 shows that the experimental groups did not differ by age, sex ratio, prior history of influenza or adverse reaction to vaccine ($p < 0.05$). Other covariables examined that were distributed similarly among experimental groups were diagnostic classification and clinic utilization rates. However, the Health Belief Model and Personal groups did contain more patients who had vaccinated last year (VLY) or anytime in the past five years than did the Control group or the Neutral group ($0.01 < p < 0.05$). Why randomization failed to distribute these variables more evenly is un-

explained and presumably due to chance. Unfortunately, information regarding prior vaccination status was missing for 68 patients (24.0 per cent); a disproportionate share of these patients (34) were in the Control group.

The vaccination rates for each of the four experimental groups are displayed in Fig. 2. Patients receiving the HBM postcard had a higher vaccination rate (51.4 per cent) than control patients (20.2 per cent) and than patients receiving a neutral postcard (25.0 per cent). Patients receiving a personal postcard also had a higher vaccination rate (41.0 per cent) than control patients.

Because the groups differed with respect to past vaccination experience, vaccination rates were computed separately for patients with different vaccination histories (Table 2). The Health Belief Model group consistently had the highest vaccination rate, no matter how the groups were divided. However, smaller and unequal cell sizes resulted in differences that were statistically significant ($0.05 < p < 0.1$) for some comparisons.

Linear logistic regression was then used to test the statistical significance of the variation of vaccination probability with the

TABLE 1. Comparison of Study Groups

	Experimental Group			
	Control	Neutral	Health Belief Model	Personal
Per cent female	65.1	63.2	68.6	75.4
Mean age $\pm$ SD (years)	68.0 $\pm$ 15.4	63.8 $\pm$ 19.6	68.1 $\pm$ 14.4	66.5 $\pm$ 16.1
History of adverse reactions to vaccine (%)	27.0	19.6	22.6	23.3
History of influenza in past (%)	22.9	25.0	20.7	38.6
Per cent vaccinated last year	34.0	34.5	51.6	51.1
Per cent vaccinated any time in past five years	45.5	44.8	65.6	63.6

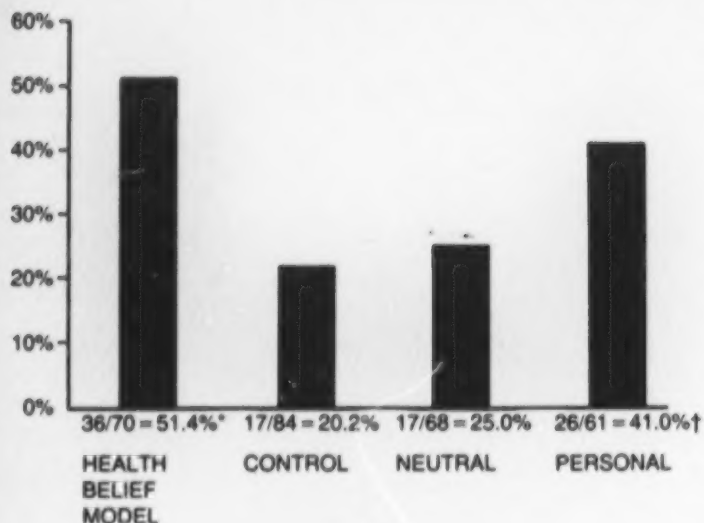


FIG. 2. Vaccination rates for experimental groups.

EXPERIMENTAL GROUP

* $\chi^2 = 16.40$, Control $\times$ H.B.M., $p < .001$ $\chi^2 = 10.32$, Neutral $\times$ H.B.M., $.001 < p < .01$ † $\chi^2 = 7.39$, Control $\times$ Personal, $.01 < p < .025$ $\chi^2 = 3.72$, Neutral $\times$ Personal, $.05 < p < .1$

following variables of interest: age, sex, experimental group, vaccination status last year (VLY), disease classification, history of adverse reactions to influenza vaccine, history of influenza in the past and utiliza-

tion status. Age, vaccination status last year and experimental group were the only variables that were found to have a significant effect on the likelihood of being vaccinated. The method of maximum likelihood

TABLE 2. Vaccination Rates and Prior Vaccination Experience

	Experimental Group				
	Control	Neutral	Health Belief Model	Personal	Combined
Patients vaccinated anytime in the past five years	45.0% (9/20)*	53.8% (14/26)	77.5% (31/40)*	57.1% (16/28)	61.4% (70/114)
Patients vaccinated last year (1977-78)	56.2% (9/16)†	63.2% (12/19)	81.3% (26/32)†	66.7% (16/24)	69.23% (63/91)
Patients not vaccinated last year (1977-78)	9.1% (3/33)‡	13.2% (5/38)	26.7% (8/30)‡	13.0% (3/23)	15.3% (19/124)

* $\chi^2 = 6.32$ (Control $\times$ Health Belief Model); $0.01 < p < 0.025$.† $\chi^2 = 3.38$ (Control $\times$ Health Belief Model); $0.05 < p < 0.10$.‡ $p = .065$ by Fischer's exact test (Control $\times$ Health Belief Model).

was used to obtain estimates of the parameters μ , α , and β in the following model:

$$\ln(p/1-p) = \mu + \alpha A + \beta x + \gamma_i$$

where p = probability of being vaccinated; A = patient age, $x = 1$ if the patient was vaccinated last year and 0 otherwise; γ_i takes on different values for the different experimental groups. The likelihood ratio criterion was used to determine the importance of the different variables with respect to being vaccinated.

After adjusting for age and VLY, the hypothesis that there is no difference in the vaccination rate among the four groups receiving either no postcard or one of the three types of postcards was tested. The value for $-2 \ln \Lambda$ was 6.5, (Λ is the likelihood ratio statistic and compares the model without the term for postcards to the model including that term). This statistic is approximately χ^2 and on 3 degrees of freedom has a $p < 0.10$ ($n = 213$). Considering only those patients who did receive postcards, the test of the hypothesis that there is no difference in the vaccination rate among groups receiving different postcards resulted in a $-2 \ln \Lambda$ of 4.5 on 2 degrees of freedom ($p < 0.01$, $n = 164$). Table 3 displays the results of the tests of the hypotheses of no difference in the vaccination rates between the two groups listed after adjusting for age and VLY. The HBM appears to be effective compared with no postcard or the neutral postcard.

Based on our data and the log-linear regression model, we obtained the fitted value for p = probability of being vaccinated for a 65-year-old as a function of vaccination history and postcard group. The data presented in Table 4 offer an estimate of the magnitude of differences between experimental groups.

Unadjusted subset analyses included patients ($n = 149$) who stated that they had never had influenza. The rates for both the Health Belief Model (53.4 per cent) and Personal (48.1 per cent) groups were signifi-

TABLE 3. Results of Tests of the Hypotheses That Vaccination Rates Are Not Different After Adjusting For Age and Vaccination Status

Test	n	$-2 \ln \Lambda$	df	p
HBM vs. Personal	108	2.0	1	< 0.25
HBM vs. Control	111	5.1	1	< 0.025
HBM vs. Neutral	118	4.4	1	< 0.05
Personal vs. Neutral	102	0.45	1	
Personal vs. Control	95	0.58	1	
Any postcard vs. Control	213	1.8	1	< 0.25

cantly higher than for the Control group (21.6 per cent, $p < 0.05$). The Neutral group's rate was mid-range (33.3 per cent). The increased vaccination rate for patients receiving the HBM card was observed for new patients who had enrolled in the clinic within the previous year, as well as for high and low clinic utilizers.

Discussion

Physicians and dentists commonly use postcards to remind patients of appointments. Studies have consistently demonstrated that postcards do lower broken appointment rates.¹⁹⁻²¹

The elements of HBM have been shown to correlate with a variety of preventive health behaviors, including influenza immunization. Our study tests the hypothesis that the combination of a cue postcard and a message emphasizing the elements of the HBM are more effective than no postcard or than a postcard containing what we have called a neutral message, simply announcing the availability of vaccine. The HBM postcard was more effective than either no postcard or the neutral postcard and remained so after adjusting for age and prior vaccination history. Furthermore, subgroup analysis showed that this effect persisted without exception in

TABLE 4. Estimates for
p = Probability of
Being Vaccinated

Age = 65 (All four experimental groups)		
Not Vaccinated Last Year	Vaccinated Last Year	
No postcard	0.10	0.57
Neutral	0.11	0.60
HBM	0.24	0.80
Personal	0.14	0.66

Age = 65 (HBM vs. Neutral Postcard)		
Not Vaccinated Last Year	Vaccinated Last Year	
Neutral	0.12	0.61
HBM	0.26	0.80

Age = 65 (HBM vs. No Postcard)		
Not Vaccinated Last Year	Vaccinated Last Year	
No postcard	0.10	0.59
HBM	0.25	0.81

the various subgroups analyzed. The consistency of the increased vaccination rates in the group receiving the HBM postcard suggests that the HBM postcard is more effective than a neutral or no postcard.

Studies of vaccination and other preventive health behaviors have also shown that physician advice correlates with compliance.¹⁶ Nonetheless, a personal postcard, designed to provide a message from the patient's personal physician, although effective overall, was not more effective after adjusting for age and prior vaccination experience. This observation does not argue that physician advice is not effective, but that the personal postcard substitute for direct physician advice used in this study was not demonstrably more effective than no postcard or the neutral postcard. Given the methodologic problems we encountered, we hope this type of cue will be restudied.

The major methodologic problem in this experimental study is the failure of the randomization to distribute prior vaccina-

tion experiences equally in the four groups. This failure reemphasizes the need to collect data on important covariables even in randomized clinical trials. Such a failure was presumably due to chance but raises the possibility that other, undetected covariables (socioeconomic status, prior health beliefs, etc.) might not have been distributed randomly. Thus, we qualify our conclusions and are especially hopeful that our study will be repeated with a more effective randomization of covariables. A nonuniversity practice setting for such a trial would be particularly appropriate, since a trial in this setting would also allow assessment of the generalizability of our results.

Another methodologic concern is the fact that we relied on patient self-report of vaccination status rather than on a more objective method. The use of telephone follow-up was necessary because almost two thirds of our patients were vaccinated outside the FMC, at such a variety of sites that objective validation of vaccination status was impossible. Although not ideal, we used self-report in our earlier study of vaccination compliance³ and found a greater than 90 per cent concordance between self-reported vaccination status and the FMC records, which suggests that the method is fairly reliable, at least in this setting.

We know of no other study that has tested various postcard reminders in this fashion. The finding that the HBM postcard was more effective is of some theoretical interest to scholars interested in the general development of the model. The general observation that retrospective studies find higher correlations between the HBM than prospective studies^{17,24,25} and the results of Cummings et al.¹⁶ showing that the HBM variables influence behavior through behavioral intention suggested that health beliefs change and may be changeable. The postcard emphasizing those elements of the HBM that

were correlated with vaccination in our earlier studies might have changed persons' "subjective probabilities"⁹ or expectations that a particular action will produce a desired outcome, perhaps by interacting with or reinforcing certain preexistent health beliefs. The change was presumably great enough to promote the desired behavior.

The results support the notion that the HBM is effective as a source of material for health-related advertising campaigns. In addition, for the practitioner, the observed effectiveness of the HBM postcard suggests that the HBM may be a useful approach in counseling designed to change unhealthy behaviors. Inui et al.²⁶ included the HBM in physician tutorials designed to improve physicians' effectiveness as managers and educators of patients with essential hypertension. Patients of tutored physicians were more compliant with drug regimens and had better control of blood pressures than patients of untutored physicians.

Regarding influenza vaccination, others have commented on the disappointingly poor compliance rate.²⁷⁻²⁹ The progressive fall in overall vaccination rate observed in the FMC patients following the swine flu scare suggests that negative attitudes of the public toward influenza vaccines may be more prevalent in the post-swine-flu era. These observations indicate a need for techniques such as effective postcard reminders to promote vaccination if vaccination of a substantial number of high-risk patients is desirable. It must be acknowledged that Sabin³⁰ has challenged the program of annual influenza immunization because of declining excess mortality associated with recent influenza epidemics and the fact that most bed disability from clinical influenza is not caused by influenza viruses. However, Sabin's analytic methods have been challenged,³¹ and many authorities do not agree with Sabin's recommendations.^{27,28,32} The Public Health Service Advisory Committee on

Immunization Practices continue to recommend yearly vaccination in spite of Sabin's conclusions.

The recent availability of pneumococcal vaccine has also focused increased attention on the general phenomenon of low utilization of vaccines designed to benefit special target populations.³³ Our study suggests that a HBM postcard is one effective way for practitioners to promote vaccines for high-risk patients in their practice. Reminder postcards can be designed to explain that patients are at high risk (i.e., *susceptible* to a potentially severe disease) for the disease for which an effective low-risk vaccine is available. A health-belief-based reminder postcard promoting influenza vaccination among high risk patients would probably be effective in promoting other vaccines like pneumococcal vaccine.

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